EXHIBIT A

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

KEVIN PHILLIPS,

Plaintiff,

vs.

C.R. BARD, INC. et al.,

Defendants.

3:12-cv-00344-RCJ-WGC

ORDER

This case arises out of an allegedly defective medical device. The parties settled during trial. Defendants have asked the Court to seal certain trail exhibits and portions of the trial transcript.

A court may "make any order which justice requires to protect the party or person from annoyance, embarrassment, oppression or undue burden or expense" upon motion by a party or a person from whom discovery is sought. Fed. R. Civ. Pro. 26(c). "The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records. *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir.2006). There is a strong presumption towards public access to judicial records. *See id.* at 1178. Under *Kamakana*, judicial records are

separated into two groups, each with its own standard to be met if litigants wish to seal them. First, judicial records attached to dispositive motions must meet the "compelling reasons" standard in order for those documents to be sealed. *Id.* at 1180. Those compelling reasons must outweigh the competing interests of the public in gaining access to the judicial records and to understand the judicial process. *Id.* at 1178–79. Second, judicial records attached to nondispositive motions must meet the lesser "good cause" standard to be sealed. *Id.* A motion to seal transcripts and evidence adduced at trial must satisfy the "compelling reasons" test, because a trial is a dispositive proceeding. *In re Elec. Arts, Inc.*, 298 Fed. App'x 568, 569 (9th Cir. 2008). The Court of Appeals has rejected requests to seal documents under the "compelling reasons" standard where the movant makes nothing more than "conclusory statements about the content of the documents—that they are confidential and that, in general," their disclosure would harm the movant. *Id.* at 1182.

Defendants argue that three categories of material should be sealed: (1) product design and testing, including confidential communications between Defendants and the FDA; (2) sales and marketing information; and (3) Defendant's internal quality control procedures, complaint and adverse event responses, reporting and handling, device tracking procedures, and corrective action procedures. The Court finds that these categories of information do not satisfy the compelling reasons test. The only harm that could come to Defendants form the release of this information is the precipitation of further lawsuits against it. Preventing lawsuits due to the release of inculpating information is not a compelling reason to seal otherwise public legal proceedings. Indeed, the exposure of facts relevant to the material claims in a lawsuit is the

purpose of a trial, and these facts should remain public unless the harm likely to result from their release is unrelated to the nature of the claims. The information does not directly implicate trade secrets.

Even if the test could be satisfied, Plaintiff correctly notes that Defendants have waived the issue because Defendants made no motion to seal the exhibits or testimony at the public trial. *See, e.g., Gambale v. Deutsche Bank AG*, 377 F.3d 133, 144 & n.11 (2nd Cir. 2004); *Littlejohn v. BIC Corp.*, 851 F.2d 673, 680 (3d Cir. 1988); *Nat'l Polymer Prods. v. Borg–Warner Corp.*, 641 F.2d 418, 421 (6th Cir. 1981); *Level 3 Commc'ns, LLC v. Limelight Networks, Inc.*, 611 F. Supp. 2d 572, 588 (E. D. Va. 2009) ("The First Amendment public right of access to these exhibits sprang into existence upon their being offered into evidence for the jury's consideration at trial, and since no request was made to seal them prior to or at that time, Savvis waived any future right to assert any competing interest to be weighed by the Court and, thus, any objection to the public availability of the exhibits in the Court's files.").

CONCLUSION

IT IS HEREBY ORDERED that the Motion to Seal (ECF No. 317) is DENIED.

IT IS FURTHER ORDERED that the Motion (ECF No. 326) is DENIED without prejudice, as it has been incompletely filed.

IT IS SO ORDERED.

Dated this 1st day of June, 2015.

ROBERT C. JONES
United States District Judge

EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEVADA

KEVIN PHILLIPS, an individual, Plaintiff, v. C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., a foreign corporation, and DOES 1 through 10, inclusive Defendants.	Civil Action No.: 3:12-cv-00344-RCJ-WGC **PLAINTIFF'S OPPOSITION TO DEFENDANTS C.R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO SEAL CERTAIN TRIAL EXIBITS AND TRANSCRIPTS**

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COMES NOW, the Plaintiff and files his Response in Opposition to Defendant C.R. Bard, Inc.'s and Bard Peripheral Vascular, Inc.'s Motion to Seal Certain Trial Exhibits and Portions of Transcripts. (Dkt. 317). This Opposition is based upon the following Memorandum of Points and Authorities, and the papers and pleadings heretofore filed herein.

Introduction

C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (Collectively referred to as "Bard") have asked this Court for the exceptional remedy of ex-post fact sealing over 200 exhibits that were published to public in open court during a 10 day trial in derogation of the common law and First Amendment rights of access to judicial documents. Of note, approximately half of these exhibits were entered into evidence by Bard itself. Plaintiff opposes Bard's motion for the following reasons: (1) Bard has waived the right to seek such protection and the documents themselves can no longer be said to contain trade secrets by nature of the fact that they were disclosed to the public in open court without any request by Defendants to seal the court; (2) Bard has failed to establish compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process and in being made aware of public safety hazards; (3) and Bard's motion does not articulate a "narrowly tailored" remedy as required when contemplating suppression of the public's First Amendment right of access to these documents.

What Bard is really asking the Court to do in this motion is to hold secret all evidence regarding what Bard knew about the risks of the Recovery Filter and its efforts to conceal, misrepresent, and downplay those risks. Not only has Bard failed to explain why it failed to request that the courtroom be seal or to establish "compelling reasons" to support these requests, such an order would fly in the face of the public policy rule enacted by the state of Nevada, in which this court sits and the Plaintiff resides, limiting what information can be sealed. The Supreme Court of the State of Nevada has held that that information evidencing a public safety hazard cannot be held secret from the public. As will be discussed below, the documents at issue in this motion, are of significant import to the public in general, and particularly to thousands of other patients who unknowingly have a unreasonably dangerous device

still implanted.[1] Therefore, Plaintiff requests that the Court enter an order denying Bard's requests to seal all records except those relating to health care records.

Procedural History

On March 20, 2011, the court granted a stipulated blanket protective order pursuant to Rule 26 of the Federal Rules of Civil Procedure. (Dkt. No. 85). The order provided a broad definition of what information could meet the "good cause" standard under Rule 26 and allowed Bard to self-designate discovery materials as protected. The protective did not modify or address Bard's burden regarding what has to be established ("compelling reasons") to hold secret documents revealed at trial. (Dkt. No. 85 ¶ 27). Further, Protective order expressly states its does not apply in any way to the use of documents at trial, and to the extent Bard intended to have any documents sealed from the public, it was incumbent on Bard to obtain a separate order from the Court.

> The terms of this Protective Order do not preclude, limit, restrict, or otherwise apply to the use of Confidential Information at trial. The use of Confidential Information during trial will be addressed in a later agreement between the parties, or, if they cannot reach an agreement, by further order of the Court.

Id.

In the course of this litigation Bard claims to have produced millions of pages of documents in response to discovery requests. Pursuant to the blanket protective, Bard designated nearly all documents produced and depositions taken as protected under the "good cause" standard.

A ten jury trial began on January 26, 2010. Prior to trial, the parties disclosed lists of documents that were to be used at trial. (Dkt. 269). The parties also disclosed prior to trial all deposition designations that the parties intended to play at trial. During the course of the trial 247 exhibits were admitted into evidence. (See, Ex. A, to Dkt. 317, Defs.' Mot. to Seal). Bard itself introduced 90 of the exhibits into evidence that it now moves to seal. At no point either prior to or during trial did Bard request that the Court room be sealed and/or that any particular document be sealed from the public.

[1] Bard sold over 30,000 of these devices, and testimony by Bard employees have revealed that only approximately 15 to 20 percent of the devices have been removed.

At trial Plaintiff pursed claims for Design and Manufacturing Defects, failure to provide adequate warnings, deceptive trade practices, and punitive damages. To support these claims, plaintiff introduced internal Bard communications and reports intended to show that (1) Bard knew or should have known the Recovery filter was not reasonably safe for human use and exposed patients to substantially higher risks than other available IVC filters, and (2) yet knowingly concealed and downplayed these risks and misleadingly marketed the filter as being as safe as all other available filters. See, *Wyeth v. Rowatt*, 244 P.3d 765, 780 (Nev. 2010)(finding that even if a warning discloses the specific injury or failure experienced, such a warning may not be adequate if Defendants downplay the risk or promote unproven benefits); Nev. Rev. Stat. Ann. § 598.0923 ("A [corporation] engages in a "deceptive trade practice" when in the course of his or her business or occupation he or she knowingly… fails to disclose a material fact in connection with the sale or lease of goods or services."); Nev. Rev. State. § 42.001(1)(providing that a corporation may be held liable for punitive damages where it willfully fails to act to avoid probable harmful consequences.). Indeed, in its Order on Defendants' Motion for Summary Judgement, the Court held that a reasonable juror could conclude that Bard's general warnings were inadequate given what it knew internally and/or that Bard could be held liable for punitive damages because under the proffered evidence, a reasonable jury could believe "that Defendants knew that their IVC filter was unsafe but continued to market and distribute it, anyway." Dkt. 194.

Thirty Days after trial had concluded by settlement, Bard moved ex-post facto to seal over 200 exhibits that were discussed and entered into evidence at the trial. This includes 190 out of the 192 exhibits that Bard alleges were communications or reports created by or received by Bard employees or consultants, which it claims to have kept confidential prior to trial. The only communications or reports involving Bard employees that Bard has not moved to seal are exhibits 674, which another court has already published to the public, and 2166, which is an FDA communication, and communications such as the instructions for use and marketing material that were undeniably distributed to the public before trial. In other words, Bard seeks a retroactive order from the court sealing all admitted exhibits that in

any way reflect what Bard knew about the risks and public safety hazards posed by the Recovery Filter, as well as its efforts to conceal, misrepresent, and downplay those risks.

Argument and Citation to Authority

I. A PARTY MAY NOT SEEK EX-POST FACTO SEALING OF EXHIBITS DISCUSSED AND ADMITTED INTO EVIDENCE IN OPEN COURT ABSENT EXCEPTIONAL CIRCUMSTANCES.

The courts have overwhelmingly denied requests seeking after-the-fact sealing of allegedly trade secret information that was disclosed in open court. *See, Warner Chilcott Co., LLC v. Mylan Inc.*, 2014 U.S. Dist. LEXIS 181576 at * 3 (D.N.J. Dec. 10, 2014); *see also*, *Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, 2013 U.S. Dist. LEXIS 45050 at *16 (W.D. Pa. Mar. 29, 2013)("Previous public disclosure of information in open court, and even outside of court, operates to waive any right to seal judicial records containing such information." "Indeed, with respect to materials used at trial, "it is well established that the release of information in open court is a publication of that information and, if no effort is made to limit its disclosure [prior to the proceeding], operates as a waiver of any rights a party had to restrict its future use."); *Fleming v. Escort, Inc.*, 2013 U.S. Dist. LEXIS 45102 (D. Idaho Mar. 27, 2013)(refusing to seal information regarding companies confidential and proprietary business and financial information because it was discussed at open trial and the moving party could not claim it was unaware disclosure was likely to occur.); *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 144 n.11 (2d Cir. 2004)(holding that "[o]nce [information] is public, it necessarily remains public" and further stating that "[o]nce the cat is out of the bag, the ball game is over"); *In re Google Inc. Gmail Litig.*, 2014 U.S. Dist. LEXIS 136420, 32-33 (N.D. Cal. Aug. 6, 2014)("In sum, where, as here, the parties did not request closure of the courtroom… and the disclosures were not inadvertent, the Court will not permit an ex post facto redaction of statements made in open court in the transcript."); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 2010 U.S. Dist. LEXIS 67631, at *10-12 (D.N.J. July 7, 2010)(denying post-hearing motion to seal transcript because information disclosed during open court is part of the public record and because "the onus is on the parties to request sealing of the courtroom prior to a hearing that will involve the

discussion of allegedly confidential information."; *TriQuint Semiconductor, Inc. v. Avago Techs. Ltd.*, 2012 U.S. Dist. LEXIS 58227 *20-21 (D. Ariz. Apr. 25, 2012)("neither party made any request prior to the proceeding to restrict public access to the proceeding. Nor did the parties take any steps to limit or object to the public disclosure of this information at the proceeding. Thus, the parties have already voluntarily 'let the cat out of the bag,' and this Court is unwilling, let alone able, to undo what is already done."). These courts reasoned that there is no authority for sealing information once it has already been disclosed in open court;[2] and that disclosure of information through use at an open trial operates as publication of that information to the public.[3] Therefore the courts concluded that if a party is aware that information may be revealed during an open proceeding that it believes should be sealed from the public, the party must move to seal the information before it is disclosed in the open proceeding. Failure to do so waives the right to have the information held secret from the public.

Here it is undisputed that the materials Bard is moving to seal were published to the public when they were discussed and admitted as trial exhibits in a trial that was open to the public. Indeed, the Court invited members of the public, who had not been selected to be on the jury, to stay and observe the trial. These materials were blown up on a large screen for everyone in the court room to see and were discussed extensively by the witnesses. Not only were these materials published to the jury at the time of trial, the transcripts discussing this information are currently available to the public.[4] Therefore, to extent that Bard was aware that these documents would be discussed and/or admitted as evidence during the trial, it has waived any right to have these materials sealed.

It is also undisputed that Bard knew this information was going to be disclosed during the trial. First, Plaintiff indicated his intention to use these materials by listing them on his exhibit list. Second, 90 of the exhibits that Bard is moving to seal were in fact introduced into evidence by Bard. Thus, Bard

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[2] *See, e.g., TriQuint Semiconductor, Inc.* 2012 U.S. Dist. LEXIS 58227 at 821 ("Indeed, the parties did not cite to, nor has the Court found, any language in *Kamakana* that references the sealing of information that has already been disclosed at a public proceeding.).

[3] *TriQuint Semiconductor, Inc. v. Avago Techs. Ltd.*, 2012 U.S. Dist. LEXIS 58227 *20-21 (D. Ariz. Apr. 25, 2012).

[4] http://www.uscourts.gov/FederalCourts/UnderstandingtheFederalCourts/DistrictCourts/FederalCourtReportingProgram.aspx (stating that during the 90 period in which transcripts are not available on PACER to allow for redaction of personal identifies, the transcripts may be viewed by the public at the Court's "public terminal."

was aware this information was going to be used during the trial and, thus was required to move to seal the courtroom to the extent that it believed any of this information should be sealed from the public. However, Bard failed to ever file a motion or even verbally request that the courtroom be sealed.

In an effort to justify ex-post facto sealing of the court record, Bard cites the *Livingston v. Isuzu Motors*, 910 F. Supp. 1473, 1480 (D. Mont. 1995) and *Jochims v. Isuzu Motors*, 151 F.R.D. 338 (S.D. Iowa 1993) cases. However, both cases are inapposite. In both cases, the courts determined that "although the trial record had not been sealed, there was no common law right of access to confidential documents used at trial." See, *Livingston* 910 F. Supp. at 1480 (describing and relying on holding in *Jochims*, 151 F.R.D. 338). This holding directly conflicts with the *Kamakana* decision holding there is a "strong presumption in favor of access" to judicial materials. *Kamakana* 447 F.3d at 1178 (9th Cir. Haw. 2006). This reasoning also conflicts with *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122 (9th Cir. Or. 2003), which held that where discovery materials, which had been made part of the judicial record but sealed before disclosure to the public, were subsequently returned to the defendant after settlement of the case, a third party could still obtain copies of those records absent a showing of "compelling reasons" that outweighed the common law right of access.[5]

The decisions in both cases also relied on the fact that although the court room was not sealed, there were protective orders that expressly governed how the material would be used at trial and that the parties did in fact treat the materials as confidential at trial. *See, Jochims*, 151 F.R.D. at 341 ("Contrary to the magistrate judge's finding, steps were taken to ensure that the confidential status of documents designated pursuant to the protective order was maintained notwithstanding their use at trial. "First, the original protective order expressly provided in paragraph 4 that the order covered designated confidential data introduced at trial, and that trial testimony and designated data would be sealed and protected from disclosure pursuant to the order."); *Livingston* 910 F. Supp. at 1480. Even assuming that the parties could unilaterally change the procedural laws governing what must be done to seal court records, the Protective order entered in this case expressly states its does not apply in any way to the use

[5] The facts of this case are discussed in greater detail below.

of documents at trial and to the extent Bard intended to have any documents sealed from the public, required Bard to obtain a separate order from the Court.

> The terms of this Protective Order do not preclude, limit, restrict, or otherwise apply to the use of Confidential Information at trial. The use of Confidential Information during trial will be addressed in a later agreement between the parties, or, if they cannot reach an agreement, by further order of the Court.

Dkt. 85, ¶ 27. Nothing in the order suggests that it modified the rule that a party seeking to preserve trade secret protection must move to seal the court room prior to the time that such information is used at an open proceeding. Here Bard not only failed to request that the courtroom be sealed but actively admitted into evidence approximately half of the exhibits it now moves to seal.

However, even if the Court were to apply the *Kamakana* test, Bard has failed to articulate compelling reasons supported by specific factual findings as to each document that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process.

II. BARD'S BURDEN OF PROOF IN SEEKING TO SEAL DOCUMENTS SUBMITTED IN CONNENCTION WITH DISPOSITIVE MOTION IS ONEROUS.

a. Standard for Sealing Summary Judgment-related Documents.

There is a default common law right of access to judicial proceedings and records. *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597, 55 L. Ed. 2d 570, 98 S. Ct. 1306 (1978). A document is deemed to be a "judicial record" if it is "filed with the court, or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings." *Pansy v. Borough of Stroudsburg, 23 F.3d 772 (3d. Cir. 1994).* A party seeking to overcome the "strong presumption in favor of access" bears the burden of overcoming this presumption by meeting the "compelling reasons" standard. *Kamakana v. City & County of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. Haw. 2006). "That is, the party must articulate compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process." *Id.* at 1178-79 (internal citations and quotations omitted). "In turn the Court must conscientiously balance the competing interest of the public and the party who seeks to keep certain

judicial records secret." *Id.* at 1179. (internal citations and quotations omitted). The presumption of access cannot be overcome by hypothesis or conjecture. *Id.*

Bard's motion relies mainly on cases applying the "good cause" standard required under rule 26(c) as opposed to the compelling reasons standard.[6] Indeed, Bard seems to argue that because the Court previously sealed similar documents under the Rule 26 "good cause" standard that this should be sufficient to seal these court records. Thus, it is important to emphasize the difference between the "compelling reasons" standard and the "good cause" standard. *Kamakana*, 447 F.3d at 1180.

Whenever a document has been filed in connection with something other than a discovery motion, even if the document had been previously sealed upon a showing of good cause, the "compelling reasons" standard applies. *Id.* at 1179-80. A "good cause" showing will not, without more, satisfy a "compelling reasons" standard. *Id.* at 1180. The Ninth Circuit explained its reasoning as follows:

> Different interests are at stake with the right of access than with Rule 26(c); with the former, the private interests of the litigants are not the only weights on the scale. Unlike private materials unearthed during discovery, judicial records are public documents almost by definition, and the public is entitled to access by default. *Id.* (citing *Nixon v. Warner Communications*, 435 U.S. 589, 597 (U.S. 1978)). This fact sharply tips the balance in favor of production when a document, formerly sealed for good cause under Rule 26(c), becomes part of a judicial record.

Id. Thus, Bard's reliance on cases discussing the "good cause" standard or the prior sealing of similar records in this case under Rule 26, do not establish compelling reasons to seal these court records.

b. What Are Compelling Reasons

Compelling reasons sufficient to outweigh the public's interest in disclosure and justify sealing court records may exist when such court files have become a vehicle for "improper purposes, such as the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." *Kamakana* 447 F.3d at 1179. However, the mere fact that unsealing such records may lead to embarrassment, incrimination, or exposure to litigation is not a compelling reason to seal court

[6] Each of the following cases cited by Bard applied the "good cause" standard to determine whether or not the at issue information should be sealed: *Phillips ex. rel. Estates of Byrd v. Gen. Motors Corp.*, 307 F.3d 1206, 1213 (9th Circuit). *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 2007 U.S. Dist. LEXIS 51828 at *7 (D.N.J. July 18, 2007); *In re Denture Cream Prods. Liab. Litig.*, Civil Action No. 09-2051-MD, 2013 WL 214672; *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.RD. 297 (N.D. Ill. 1993); *In re Eli Lilly & Co., Prozac Products Liability Litigation*, 142 F.R.D. 454 (S.D. Ind. 1992); *In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653, 659 (D.N.J. 2004); *Smithkline Beecham Corp. v. Synthon Pharmaceuticals Ltd.*, 210 F.RD. 163 (M.D.N.C. 2002); *Medicis Pharm. Corp. v. Acella Pharm., LLC*, CV 10-1780-PHX-JAT, 2012 WL 2260928 at *2 (D. Ariz. June 15, 2012).

records. See, e.g., *Kamakana* 447 F.3d at 1179; *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1137 (9th Cir. Or. 2003).

Bard also seems to argue that because it allegedly produced these documents in reliance on the blanket protective order, which allowed it to unilaterally designate documents as confidential; this somehow serves as a compelling reason to seal all such documents that were used at trial. (See, Dkt. 317 p. 3, Ln: 6-8). However, this argument has been expressly rejected by the Ninth Circuit. See, *Foltz* 331 F.3d at 1138.

In *Foltz*, consumers sued State Farm alleging that it defrauded them of personal injury insurance coverage owed to them. *Id.* at 1128. The parties agreed to "a blanket protective order [,which was] designed to keep secret all other "confidential information" produced by the parties in discovery and/or filed with the court, absent agreement or an order by the district court. *Id.* After four years of litigation, the parties settled and requested the court file be sealed. In November of 1998, the district court entered a final order of dismal and pursuant to a stipulated order released the court file to State Farm. *Id.* In 1999, several public interest groups and private parties moved to unseal the court records and to gain access to discovery material. *Id.* The district court denied access to approximately 85 documents that be been filed with the court, including discovery documents. (*Id.* at 1136).

State farm argued that the compelling reasons standard was met in part because, "it relied on the confidentiality provisions of the protective order issued by the district court in consenting to discovery requests and settling the *Foltz* litigation." *Id.* at 1137. The Ninth Court determined, however, that where a blanket protective order did not require a court to make good cause findings as to individual documents before they were produced, a party's alleged reliance on the blanket protective order in producing document cannot be a compelling a reason to overcome the presumption in favor of public access. *Id.* at 1138. The protective order in this case is blanket protective order, which allowed Bard to self-designate documents as confidential without any findings required by court as to individual documents or even categories of documents. See, Dkt. 85. Thus, the fact that there is a protective order in this case does not support a finding of compelling reasons sufficient to overcome the public's right of access.

Bard also seems to argue that confidential business information alone rises to level of information protected under the compelling reasons standard. However, the courts have repeatedly held that confidential information has to arise to level trade secret for it meet the compelling reasons standard.

See, Republic of Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 663 (3d Cir. 1991), *quoting Littlejohn v. BIC Corp.*, 851 F.2d 673, 685 (3d Cir. 1988)("[b]usiness information alleged to be confidential is not entitled to the same level of protection from disclosure as trade secret information".) *Jones v. Colo. Cas. Ins. Co.*, 2014 U.S. Dist. LEXIS 167407, 4-6 (D. Ariz. Dec. 3, 2014)(Moreover, because "confidentiality alone does not transform business information into a trade secret," a party alleging trade secret protection as a basis for sealing court records must show that the business information is in fact a trade secret."); *St. Clair v. Nellcor Puritan Bennett LLC*, 2011 U.S. Dist. LEXIS 129152, 3-4 (D. Ariz. Nov. 7, 2011)("Although Nellcor asserts that the exhibits contain confidential business information, confidentiality alone does not transform business information into a trade secret.")

III. THERE IS SUBSTANTIAL PUBLIC INTEREST IN THE INFORMATION BARD IS MOVING TO SEAL

The public has a strong interest in the subject matter of this trial, both in general to ensure that justice is being done in its court, and in the matters specific to this trial. As a general matter, the public has a right to learn what occurred during this trial. "Indeed, the common law right of access to federal courts is designed to promote "a better understanding of the operation of government as well as confidence in and respect for our judicial system." *Publicker Indus., Inc. v. Cohen*, 773 F.2d 1059, 1070 (3d Cir. 1984). Further the public has a financial stake in this trial. *See, Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, 2013 U.S. Dist. LEXIS 45050 at * 30 (W.D. Pa. Mar. 29, 2013). Tax payer dollars underwrite salaries of Court personnel, juror expenses, and the space afforded to the parties in the courthouse. A long trial and complicated litigation like this case incurs great costs on the Court in a time when the judiciary is under tight financial restrains. Tax payer dollars underwrite salaries of Court personnel, juror expenses, and the space afforded to the parties in the courthouse. Thus, "what transpired in the court room is public property." *Craig v. Harney*, 331 U.S. 367, 374, 67 S. Ct. 1249 (1947).

The Public also has a right to know of evidence indicating the existence of a public safety hazard, and whether a company has tried to conceal or misrepresent the risks associated with its products. On January 1, 2008, the Nevada Supreme Court adopted a public policy rule that "[i]n no event may the sealing or redaction [of court records] have the purpose or effect of concealing a public hazard." Nev. S.C.R. 3(5)(a). Similarly, courts have held that the public has a right to know whether a company has

tried to conceal and/or failed to take appropriate safety steps regarding dangers it is aware of in one its products. *See*, *Culinary Foods v. Raychem Corp.*, 151 F.R.D. 297 (N.D. Ill. 1993).

In *Culinary Foods,* the plaintiff filed a product liability claim alleging that the manufacturer was aware of the dangers and defects in a pipe that led to a fire and yet continued to manufacture and market the device. 151 F.R.D. 297 (N.D. Ill. 1993). The court held that to the extent that discovery provided evidence that the manufacturer knew of the dangers and either failed to take action or attempted to conceal the information, that such information could not be sealed even under the "good cause" standard. *Id. at* 301. The court explained:

> Although the information regarding the hazards of products and the corporation's knowledge of the information may be embarrassing and incriminating, this alone is insufficient to bar public disclosure. Furthermore, where trade secrets are not at issue, common sense would indicate that the greater a corporation's motivations for secrecy, the greater the public's need to know. In addition, we agree … it is inconceivable to this court that under such circumstances the public interest is not a vital factor to be considered in determining, whether to further conceal that information and whether a court should be a party to that concealment.

Id. (internal quotations and citations omitted).

Here the general public as well as those 20,000 or so patients that still have a Recovery filter implanted have substantial interest in knowing information which Bard has withheld from the public suggesting the Recovery filter exposes patients to increased risk, that Bard knew the device was not reasonably safe for human use, and that Bard purposefully downplayed and concealed these risk while actively marketing the Recovery filter as being just as safe as all other available IVC filters. Bard's exhibits which it retroactively seeks to seal reveal, among other things, the public safety information discussed below.

In premarket development, Bard determined that the to be reasonably safe for human use the device had to be able to resist the maximum physiologic pressure that could be seen in the vena cava below the filter. Exs. 1092, 1094, 1096, 1097, 2027. Bard then relied on animal testing to state that the maximum pressure that could be reached was 35 millimeter of mercury ("mmHg"). *Id.* Bard then added a safety factor of 15 mmHg and established a minimum safety specification of 50 mmHg of physiologic pressure below the filter that all Recovery filters had to be able to resist in a simulated vena cava. *Id.*

Based on this testing, Bard concluded that the Recovery Filter would never migrate when challenged by clot. *Id.*

However, Bard misstated the results of the animal testing. *Id.* The animal testing actually demonstrated physiologic pressure levels below the filter well in excess of 55 mmHg. *Id.* Thus, Bard knew that its minimum safety specification regarding migration resistance was set artificially low. This was confirmed in late 2003 and early 2004, when numerous patients began suffering death and serious injuries because the Recovery filter was being dislodged by clot challenges. Ex. 860. This in turn led to a design investigation in early 2004 that confirmed Bard's minimum safety specification of 55 mmHg was dangerously too low.

These tests, as well as subsequent testing, revealed that the Recovery filter failed to meet even Bard's artificially low minimum safety specification regarding migration resistance. *See, e.g.* Ex. 1058, 792, 2215, 2469. The tests further revealed that the Recovery filter had substantially less ability to resist migration than other available filters, including the Simon Nitinol filter. See, e,g. *Ex.* 1058. As part of this investigation, Bard also spoke to its two medical consults Dr. Venbrux and Kaufman, who warned Bard that Recovery filter's minimum safety specification for migration resistance was inadequate and should be increased by almost 300%. (See, Ex. 1152). These consultants further warned Bard that the Recovery was a "wimpy" filter that needed stronger radial force to assure stability. *Id.* Plaintiff has attached Exhibit 1152, hereto as Ex. A, so that there court can see there is no imaginable basis for Bard to claim that it reveals trade secrets.

Bard's investigations into why the Recovery Filter was unable to remain stable and was causing patient death and serious injury concluded that the device was migrating because one of two things were occurring. *See*, Ex. 860. Either the physiologic force exerted on the filter from below due to thrombus challenge was exceeding the ability of the anchoring system of the device to hold stable, or a pressure spike in the vena cava was leading to distension beyond the "design limitations" (leg span/width) of the device. *Id.* in contrast, Bard in its Dear Dr. letters reported to the public that it did not know what was causing these migration events. See, Ex. 2014, May 11, 2005 Dear Dr. letter stating, "Even though we have conducted a comprehensive investigation into each of the reported events, we have been unable to fully understand the etiology, including any association with prophylactic placement.").

Notably, in modifying the design of the Simon Nitinol Filter, Bard had substantially reduced the leg span/width of the Recovery Filter. Mr. Carr testified at trial that he was aware that distension of the vena cava beyond on the width of the filter or beyond the 28 mm indicated vena cava size could occur after placement and that this would result in reduced migration resistance or outright migration of the filter. Yet, these documents show that prior to putting the device on the market Bard choose to never test the device to determine if the reduced leg span of the filter still provided a sufficient margin of safety to accommodate caval distension. Further, subsequent testing confirmed that even if the device did not immediately migrate when a vena cava expanded beyond 28 mm, that the migration resistance of the filter dropped below the established minimum safety specification of 50 mmHg. *See, e.g.* Ex. 1058, 792, 2215, 2469). Bard has never revealed these facts to the public or the FDA.

These documents also establish that Bard was aware that the Recovery Filter had statistically significant and substantially higher reported failure rates, including for death, migration, perforation and fracture than all other devices. Moreover, Bard determined that there was a strong inverse correlation between its higher reported failure rates for migration and the test results it conducted as part of the special design review in early 2004. This information is revealed in the November 2004 Consultant Report and Bard's December 2004 Health Hazard Evaluation Exs. 1190 and 862. These documents also warn Bard that this information is not known to consumers and suggests that Bard considers warning them of the higher reported failure rates. Ex. 862. These higher reported failure rates are also seen as simple data summaries or reports of customers who have stopped using the filter because they became aware of the increased failure rates or just individual failures. *See,* Exs. 536, 1046. Plaintiff has attached these for the Court convenience as Exhibit B, so that the Court can see that these documents in no way reveal trade secrets.

Based on this data and Bard's safety policy regarding recalls and products corrections, Bard's head of Quality Assurance, Doug Uelmen, testified that the Recovery filter posed an unacceptable risk to human health and required product correction.

Similarly, a Health hazard Evaluation from July 9, 2004 reveals that Bard knew that the Recovery filter was reported to fracture at a rate that was 28 times higher than all other available devices. (Ex. 864)

Despite all of these facts, the exhibits demonstrate that Bard was instructing sales force that if anyone raised concerns regarding the safety of the device that they were to provide factual misrepresentations assuring consumers that the Recovery filter was a safe device because it had the same failure rates as all other devices. *See*, Exs. 669, 680, 970, attached hereto as Ex. C. Further, Bard continued to use its marketing piece, Exhibit 1030, throughout the life cycle of the product, which represented the Recovery filter was safer than all previous IVC filters.

These exhibits also show that Bard established "Crisis Communication team" and retained a publicity firm for the specific purpose of preventing the spread of knowledge about the migration hazard posed by the Recovery filter. See, Exs. 517, 682, attached hereto as Ex. D.

The exhibits also reveal acknowledgements that Bard was aware of the safety problems with its device and yet chose to conceal and downplay those risks. See, e.g. 748,[7] 689, 978, attached hereto as Ex. E.

To date, Bard has failed to ever warn the public that the recovery filters anchoring mechanism may have been deficient; that it set the migration resistance specification to low; that multiple tests showed that even when perfectly deployed, the device failed to meet its own minimum safety specifications; that when tilted, in a vena cava that distends, or when one or more struts have fractured, the device fails to meet a minimum safety level for migration resistance; that multiple test confirmed the Recovery filter is less able to resist clot challenges than other devices; that the Recovery filter was known to have substantially higher reported failure rates than all other devices; or that according to Bard's own policy and procedure, the device was not reasonably safe for human use. Thus, these documents contain information revealing a public safety hazard and Bard's efforts to downplay and conceal that hazard from the public.

IV. BARD HAS FAILED TO ESTABLISH SPECIFIC FACTS ESTABLISHING COMPELLING REASONS OUTWEIGHING THE STRONG PRESUMPTION OF ACCESS TO COURT RECORDS

To establish that these documents contain trade secrets, Bard must articulate compelling reasons supported by specific factual findings that each document contains "a formula, pattern, device or

[7] Sales Manager noting he could not imagine a worse situation than what existed with the Recovery Filter in 2004 and 2005 and that Bard's marketing Manager should be proud because it was "a terrible situation that was held together with scotch tape, smoke, mirrors, crying, etc."

compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who not know it or use it" in additional evidence that Bard took reasonable steps to keep the information secret. *See*, Nev. Rev. Stat. § 600A.030(5), *Electronic Arts, Inc. v. United States District Court*, 298 Fed. Appx. 568 (9th Cir. Cal. 2008)(adopting definition of trade secret stated in Restatement of Torts, 757, Comment b (1939)). Information is not regarded as a trade secret if it is "fully disclosed by issued patents; generally known to those skilled in the industry or trade; or consist[s] of information easily acquired by persons in the industry from patents, literature or known processes freely available." *Motorola, Inc. v. Fairchild Camera & Instrument Corp.*, 366 F.Supp. 1173, 1186 (D.Ariz. 1973); *Bowser, Inc. v. Filters, Inc.*, 398 F.2d 7, 9 (9th Cir. Cal. 1968) ("The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret."). Here, Bard has failed to produce facts allowing for such a particularized finding.[8]

In support of its claims, Bard argues generally that there are compelling reasons to ex-post facto seal all documents that in any way reflect or relate to its "design and testing" of the Recovery filter, its "sales and marketing" efforts for the Recovery filter, and its "quality system procedures, complaint and adverse event responses, reporting and handling, device tracking procedures, and corrective action procedures" relating to the Recovery filter because the medical device industry is competitive and that "these documents reflect the confidential business processes that Bard uses across its product lines to design and these documents would reflect "the confidential business processes that Bard uses to design, develop, market, and track its product, and to investigate and exercise quality control over its products." Dkt. 317, p. 8. These claims are insufficient for numerous reasons.

First, Bard's claims fail because this information and the documents themselves were all published to the public in open trial and the transcripts discussing these documents are currently available to the public via the "public terminal." Once these documents were published in open court,

[8] To that extent that Bard is arguing confidential business information not reaching the level of trade secret may provide compelling reasons to overturn the presumption of access, the law holds otherwise. *See, Jones v. Colo. Cas. Ins. Co.*, 2014 U.S. Dist. LEXIS 167407, 4-6 (D. Ariz. Dec. 3, 2014); *St. Clair v. Nellcor Puritan Bennett LLC*, 2011 U.S. Dist. LEXIS 129152, 3-4 (D. Ariz. Nov. 7, 2011).

this information could no longer be considered secret and thus there is no harm from further disclosure. *See, Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, 2013 U.S. Dist. LEXIS 45050 at *16 (W.D. Pa. Mar. 29, 2013)(finding that even if PowerPoint slides had contained trade secrets, the use of them in an open proceeding operated as a publication to the public meaning the documents could not meet trade secret definition.); *Fleming v. Escort, Inc.*, 2013 U.S. Dist. LEXIS 45102 (D. Idaho Mar. 27, 2013)(refusing to seal information regarding companies confidential and proprietary business and financial information because it was discussed at open trial and the moving party could not claim it was unaware disclosure was likely to occur.); *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 144 n.11 (2d Cir. 2004)(holding that "[o]nce [information] is public, it necessarily remains public" and further stating that "[o]nce the cat is out of the bag, the ball game is over"); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 2010 U.S. Dist. LEXIS 67631, at *10-12 (D.N.J. July 7, 2010)("In otherwords, there should be no backdoor attempt to 'seal the courtoom." "Once a hearing is conducted in the open court, information placed on the record is just that: information that is on the *record*."); *TriQuint Semiconductor, Inc. v. Avago Techs. Ltd.*, 2012 U.S. Dist. LEXIS 58227 *20-21 (D. Ariz. Apr. 25, 2012) ("[I]t cannot be said that the parties are seeking to retain the secrecy of any of the information disclosed in the transcripts, for this information has already entered the public domain. There is thus an inherent logical dilemma underlying the parties' requests because information that has already entered the public domain cannot in any meaningful way be later removed from the public domain."); Further, Bard failed to take reasonable steps to keep this information secret, such as requesting the courtroom be sealed.

Second, Bard fails offer any evidence supporting these claims, such as affidavits or even the documents themselves. Statements in a brief are not evidence and are insufficient to justify a motion to seal, at least in the absence of a stipulation or joint representation by all parties which details the confidential nature of the information. *Cochran v. Volvo Grp. N. Am., LLC*, 931 F. Supp. 2d 725, 730 (M.D.N.C. 2013); *see also INS v. Phinpathya*, 464 U.S. 183, 188 n.6, 104 S. Ct. 584, 78 L. Ed. 2d 401 (1984) (declining to consider "[c]ounsel's unsupported assertions in respondent's brief" as evidence); *Kulhawik v. Holder*, 571 F.3d 296, 298 (2d Cir. 2009) ("An attorney's unsworn statements in a brief are not evidence."); *Martin v. Cavalier Hotel Corp.*, 48 F.3d 1343, 1358 (4th Cir. 1995) (holding jury was properly instructed that counsel's statements are not evidence); *Estrella v. Brandt*, 682 F.2d 814, 819-20 (9th Cir. 1982) (holding legal memoranda and oral argument are not evidence); *Skyline Corp. v. NLRB*,

613 F.2d 1328, 1337 (5th Cir. 1980) ("Statements by counsel in briefs are not evidence."). While, Bard states in footnote 3 of its brief that a supporting declaration by Rob Carr will be attached as Exhibit A, no such declaration was provided. Footnote 3 also claims that this same declaration was filed in connection with a motion to seal documents that were attached to Plaintiff's opposition to Bard motion for summary judgment at Docket No. 188. However, a review of the Docket demonstrates that no such declaration was attached there either. Thus, Bard has offered no actual evidence supporting any of its claims.

Third, other than vague generalities, Bard offers no specific grounds or reasons why disclosure of specific documents would put it at any potential competitive disadvantage or provide Bard's competitors with an economic advantage. Nor can such a showing be made. The information contained in these documents has no inherent or intrinsic actual or potential value. Bard does not identify what policies and procedures these documents would allegedly reveal, how the information in these documents would actually reveal such information, or how these policies and procedures differ from those generally known and used in the industry. Having reviewed these procedures, they are in fact predominantly simply reformatted copies of the FDA's good practice manufacturing guidelines that govern design, marketing, quality control and post-market surveillance. Furthermore, the information is stale, and involves a product which has not been sold since 2005. *See, Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, 2013 U.S. Dist. LEXIS 45050 at *36 ("Disclosure of such past profit analysis, sales figures, and other finical data has not been shown to cause the *current* competitive harm that sealing is intended to prevent.) Bard has not offered any evidence that any of the policies and procedures it used from 2004 through 2006 are still in place today. Similarly, the manufacturing process for the Recovery filter has certainly been replaced, as the Recovery filter and each generation since up to the Meridian Filter have been removed from the Market. Bard now only sells the Denali removable filter, which has a different design, manufacturing process, and is cut from one piece of metal. Bard's competitors inarguably have no use for information that merely points out obvious design flaws and potential changes based on publicly available materials from years ago regarding products that are no longer on the market.

While it is understandable that Bard wishes to keep the public from discovering the true risks of the Recovery Filter and Bard's efforts to conceal and misrepresent those risks, there is nothing in these documents that would provide any value to any competitor, or to Bard in keeping them a secret from its

competitors. Further, as discussed above, evidence of knowledge of dangers posed by a device and a company's efforts to conceal or downplay such information is not compelling reason.

The same attorneys and defendant involved in this matter recently made the same baseless arguments in a multidistrict litigation relating to its defective transvaginal mesh device. *See*, *In re C. R. Bard, Inc. Pelvic Repair System Prods. Liab. Litig.* 2013 U.S. Dist. LEXIS 70189 (S.D. W. Va. May 17, 2013). Bard is also represented by Richard North, Taylor Daly, and Matthew Lerner in that case. A discovery dispute arose in those proceeding regarding whether two categories of materials were trade secret. The first set consisted of emails indicating that that Bard had knowingly marketed materials for permanent implantation, which the supplier represented should not be used for permanent implantation. *Id. at* *14. The second set of materials involved four internal memoranda that "Bard contends revealed the internal thought processes, testing, analysis, hypothesis and research and development methods both for products in development at the time the documents were written and for future development. *Id. at* *18-19. The court rejected Bard claims of trade secret because Bard's claims were conclusory and unsupported. *Id.* at 16-19. The court explained:

> Bard's statements do not indicate the reasons why such information is trade secret or otherwise entitled to protection. Bard does not explain how such information, in the hands of a competitor, would inflict harm.

Id. at *19.

Bard's failure to provide specific factual support for its claims of trade secrets is strikingly similar to the facts in *Biocore, Inc. v. Khosrowshahi*, 96 F. Supp. 2d 1221, 1231-32 (D. Kan. 2000) ("*Biocore*"). In *Biocore,* a company conclusory alleged that its business procedures for conducting clinical trial studies and for obtaining FDA approval under FDA regulations were trade secrets. As in the present matter, *Biocore*, the plaintiff, failed to produce evidence describing the procedures, failed to explain how its procedures differed from others in the field or from the general FDA requirements. The court ruled that *Biocore* had failed to establish the documents were trade secret because "[p]laintiffs failed to meet their burden of proving that their method of conducting efficacy studies is different from methods that are matters of general knowledge in the trade." *Id.* at 1231. The court explained its decisions as follows:

> While both of these items are marked confidential, they contain nothing but basic information. Plaintiffs do not show that the validation protocol and validation procedures are not generally known. They provide no evidence regarding protocols and procedures which other companies use. Neither document describes any procedure that appears to be out of the ordinary; the documents list obvious procedures which every company in the field would also follow with slight but obvious variations for specific equipment and products.

Id. at 1232 (internal citations omitted). As in *Biocore*, Bard has failed to provide anything beyond general and unsupported claims.

Bard's reliance on the *Selling Source, LLC v. Red River Ventures, LLC*, 2011 U.S. Dist. LEXIS 49664 (D. Nev. Apr. 29, 2011) in unavailing for several reasons. First, it is an unpublished opinion by a district court wherein both parties stipulated that the documents were trade secret. Second, there was no claim that the material revealed a company's knowledge of a public safety hazard or efforts to conceal such hazard from the public. Third, the allegedly protected materials involved evidence of the company's current business model and customer base. In this case, all documents evidence Bard's knowledge regarding the risk of the Recovery Filter and its efforts to conceal such information as of more than eight years ago. Even if this information could have been considered trade secret at one time, the information is long since stale and of no value to competitors. Fourth, this case, unlike *Biocore* and the present matter, did not involve a medical device company whose actions are governed by FDA regulations, wherein the industry as whole has adopted certain uniform procedures that simply mimic FDA minimum safety regulations. Finally, unlike here, these documents do not evidence detailed information regarding Bard's business operations, customer agreements, corporate structure, or how Bard licenses products to customers. What this case does establish, however, is that to meet the "compelling standard" a company must at minimum establish that the materials are subject to trade secret. *Id.* at *18 (noting that where a joint motion to seal was based on a claim that the dispositive motion contained information related to the parties' propriety business operations and trade secrets, the information could only be sealed if it arose to the level of a trade secret.).

Bard reliance on *Spectrum Pharms., Inc. v. Sandoz Inc.*, 2014 U.S. Dist. LEXIS 117196, 4-5 (D. Nev. Aug. 21, 2014) and *Clark v. Metro Life. Ins. Co.*, 2010 WL 10006823 (D. Nev. Mar. 16, 2010) are also misplaced. Neither of these cases involved information relating to a product that had been off the market for years or that revealed a public safety hazard. For example in *Spectrum Pharms.*, the case dealt with a company's manufacturing procedures, product composition, and years of efforts to obtain

approval of pharmaceutical that was not yet approved by the FDA. The court noted its concern that a competitor could use the information to produce its own product and to gain FDA clearance. This inapposite of the present matter, where the Recovery filter was removed from the market due design problems and even its three subsequent generations providing for design fixes have been removed as well. There is no legitimate economic interest in a company brining an unsafe product to market. Further, these cases offer little analytical value, as there is little to no explanation of what the documents actually consisted of and why the Court believed the individual documents would provide economic value to competitors.

For the convenience, Plaintiff has attached examples of documents clearly showing examples of documents of which there is no reasonable claim of trade secret protection. *See,* Exs. A-E.

V. CONCLUSION

Based on the forgoing, Plaintiff requests that the Court enter an order denying Bard's requests to seal all trial exhibits and transcripts other than those relating to health care records. .

Dated this the 27th day of March 2015.

LOPEZ McHUGH L.L.P.

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EXHIBIT C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: **BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION**	MD No. 2641 **STIPULATED PROTECTIVE ORDER**

The parties, through their respective counsel, stipulate to the entry of a protective order to govern the dissemination of documents, materials, and other information, including the substance and content thereof, designated by any party as confidential and produced by any party in support of motions, in response to written discovery, or during any formal or informal discovery in this litigation subject to the terms as set forth below.

WHEREAS, the defendants to this action, through their counsel, have requested of the plaintiffs that a protective order preserving the confidentiality of certain documents and information should be entered by the Court.

THEREFORE, IT IS ORDERED as follows:

I. Definitions

1. **Confidential Information**. "Confidential Information" is defined herein as any information that constitutes, reflects, discloses, or contains: (1) a "trade secret" or other confidential research, development, or commercial information" that is suitable for protection under Federal Rule of Civil Procedure 26(c)(1)(G); and (2) information that may be protected from disclosure under a party's constitutional right of privacy such as

confidential and private psychiatric, psychological, medical condition and/or employment information.

2. **Trade Secret**. A party, in designating information "Confidential" because it contains a "Trade Secret", shall designate only information that meets the definition of trade secret contained in 18 U.S.C.A. §1839 (West):

> the term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if --
>
> (A) the owner thereof has taken reasonable measures to keep such information secret; and
>
> (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

3. **This Action**. "This Action" means IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION, MDL No. 2641, pending in the transferee district, the United States District Court District of Arizona, as per the Transfer Order issued by the United States Judicial Panel on Multidistrict Litigation on August 17, 2015 (Doc. 31) and all cases filed in or transferred to the District of Arizona as a result of the Transfer Order in the above captioned matter.

II. Information Within the Scope of the Protective Order

4. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during This Action, including all copies, excerpts summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any party to This Action or its representatives (the "Supplying Party") to any other party or parties to This Action or their representatives (the "Receiving Party"), whether provided voluntarily, pursuant to formal discovery procedures, or otherwise.

5. The scope of confidentiality protections afforded under this Protective Order does not include any trial exhibits or trial testimony entered into evidence during the case known as *Phillips v. C.R. Bard, Inc., et al.*, No. 3:12-cv-00344-RCJ-WGC (D. Nev. June 1, 2015) (*See*, **Exhibit C**, Order denying Bard's motion to seal trial exhibits and trial transcripts, Doc. No. 328). Notwithstanding the foregoing, this Protective Order does not address or alter whether or not Defendants may argue that non-confidential documents should still be entitled to protection under the work-product doctrine and/or the attorney-client communication privilege.

III. Designating Information As "Confidential" Pursuant to This Protective Order

6. **Documents**. Any Supplying Party producing documents that contain information that meets the definition of Confidential Information as provided in Paragraph 1 and 2 herein, may designate the contents of the documents as "Confidential" prior to or at the time of production by placing the following designation on the documents: "CONFIDENTIAL – Subject to Protective Order". Where a document consists of more than one page, each page of the document shall be designated as such. Any document or information for which it is impracticable or impossible to affix such a legend may be designated by written notice to that effect with a reasonable description of the material in question including a BATES number, where applicable.

7. If a Supplying Party makes documents or information available for inspection, rather than delivering copies to another party, no "Confidential" designation is required in advance of the initial inspection. For the purposes of initial inspection only, the documents shall be considered "CONFIDENTIAL". Upon production of the inspected documents, the Supplying Party shall designate which of the produced or copied documents and materials are or contain Confidential Information pursuant to Paragraph 6 of this Order.

8. **Written Discovery**. If responses to written discovery contain Confidential Information as defined in Paragraph 1 and 2 of this Protective Order, the Responding Party may designate the responsive documents and information, as set forth in

Paragraph 6, with specific indication of the page and line references of the material that is "Confidential" under the terms of this Protective Order.

9. **Depositions**. The parties may designate as Confidential any deposition transcript, or portions thereof, in This Action that meets the definition of Confidential Information provided in Paragraphs 1 and 2 of this Protective Order. Counsel for the designating party shall advise the court reporter and the parties on the record during the deposition or by letter no later than thirty (30) calendar days after the court reporter provides the parties with the final deposition transcript. If any portion or all of a deposition transcript is designated as Confidential Information, the court reporter shall label the cover page of the original and one copy of the transcript to state that Confidential Information is contained therein, and shall label as "Confidential" each page of the transcript and/or exhibits to the deposition transcript that constitute "Confidential Information". Confidential designations of transcripts or portions thereof, apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript or portion thereof prior to the expiration of the 30-day period as "DO NOT DISCLOSE – SUBJECT TO FURTHER CONFIDENTIALITY REVIEW." Deposition transcripts or portions thereof will be treated as Confidential Information until expiration of the 30-day period. If any party does not designate the transcript as "Confidential" either at the time of the deposition or within the 30-day period defined above, no portion of the entire transcript will be deemed "Confidential" and the "DO NOT DISCLOSE-SUBJECT TO FURTHER CONFIDENTIALITY REVIEW" legend shall be removed. The 30-day period may not be extended without mutual agreement of the parties.

10. **Confidential Information Produced By Third Parties**. A party in This Action may designate as Confidential any document, information, or testimony produced or supplied by any person or entity not a party to This Action, that constitutes or meets the definition of Confidential Information as defined in Paragraphs 1 and 2 of this Protective Order. The party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any party receiving information from a

third party shall treat such information as Confidential Information during this thirty (30) day period while all parties have an opportunity to review the information and to determine whether it should be designated as confidential. Any party designating third party information as Confidential Information shall have the same rights, duties, and obligations, as a Supplying Party under this Protective Order.

11. **Publicly Available Information.** The confidentiality restrictions and confidentiality obligations set forth herein shall not apply to information that is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party, generally available to the public through publication or otherwise. This includes information published during public hearings and trials, if the Supplying Party does not move to seal or appeal any order denying such motion to seal within the time permitted under the applicable rules. Notwithstanding the foregoing, this Protective Order does not address or alter whether or not Defendants may argue that non-confidential documents should still be entitled to protection under the work-product doctrine and/or the attorney-client communication privilege.

IV. Limitations on Use of Confidential Information

12. All Confidential Information shall be used for the purpose of this lawsuit only, and except as permitted by this Order, the parties and their respective attorneys, as well as experts or consultants, shall not give, show, or otherwise divulge or disclose the Confidential Information, or any copies, prints, negatives or summaries thereof to any person or entity. Notwithstanding the foregoing provisions of this paragraph, nothing in this Order shall prevent the use of any of the documents or electronically stored information ("ESI") produced pursuant to this Protective Order in other actions brought by the plaintiff's counsel, so long as a comparable protective order is entered in those other actions.

13. Confidential Information pursuant to this Protective Order shall be treated by the parties, their counsel, and any other signatory to this Protective Order as being confidential and private. Any copy of Confidential Information shall have the same status

as the original. The disclosure and use of Confidential Information shall be confined to the permissible disclosures and uses set forth in this Protective Order, and no one shall disclose or use Confidential Information in a manner inconsistent with the terms and the intent of this Protective Order.

14. Confidential Information may be disclosed only to the following persons and shall be used solely for the litigation of This Action and may not be disclosed to anyone not authorized under this paragraph:

a. Parties, their representatives, in-house counsel and regular employees who are actively engaged in, or actively overseeing This Action;

b. Counsel of record, their associated attorneys, and support staff, including paralegal and secretarial personnel who are working on This Action;

c. Experts and consultants (including their employees/contractors) who are consulted or retained by a party to assist in the litigation of This Action;

d. Third-party contractors and their employees who are consulted or retained by one or more parties to provide litigation-support or copy services in connection with the litigation of This Action

e. Witnesses or prospective witnesses in This Action;

f. Court reporters, videographers, and other persons involved in recording deposition testimony in This Action;

g. The Court and its personnel, including any mediators and/or special masters appointed by the Court, or if an appeal, the court with appellate jurisdiction; and

h. Jurors in This Action

15. Prior to the disclosure of any Confidential Information to any person identified in Paragraph 14 above (except the Court and its personnel and jurors in This Action), the disclosing party will provide each potential recipient of Confidential

Information with a copy of this Protective Order, which said recipient shall read. Upon reading this Protective Order, such person shall sign an Acknowledgment, annexed to this Protective Order as **Exhibit A**, acknowledging that he or she has read this Protective Order and shall abide by its terms. Notwithstanding the foregoing provision, Confidential Information may be disclosed to a witness who will not sign an Acknowledgment in a deposition at which the party who has designated the Confidential Information is represented or has been given notice that Confidential Information produced by the party may be used. These Acknowledgments are strictly confidential and shall be maintained by counsel for each party and only with good cause shown and separate court order will the Acknowledgments be disclosed to the opposing side. Persons who come into contact with Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgments but must comply with the terms of this Protective Order.

16. All persons receiving or given access to Confidential Information in accordance with the terms of this Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Order and remedying any violations thereof.

17. Confidential Information shall not be placed or deposited in any sort of data bank that is made available for indiscriminate or general circulation to lawyers, litigants, consultants, expert witnesses or any other persons not working on This Action and not signatories to this Protective Order. This paragraph and the other provisions of this Order shall not apply to materials which, if challenged by any party, the Court rules are not entitled to protection. This paragraph does not limit or restrict in any way the manner in which a party may store and make Confidential Information available to the attorneys, support staff, experts, and any other persons or entities working on This Action, provided the general terms of this Order are followed.

18. The parties and their counsel as well as their technical consultants and experts shall also not sell, offer, advertise, publicize nor provide under any condition any Confidential Information produced by any other party to any competitor of any defendant

or to any employee or any competitor (irrespective of whether they are retained as an expert by a party in This Action).

19. In the event that either of the parties is served by a non-party with a subpoena for Confidential Information that was originally provided and claimed as Confidential by another party, the Receiving Party will give notice to the Supplying Party, where reasonably possible, no less than ten (10) business days prior to disclosure by providing a copy of the subpoena, to allow a reasonable opportunity for the Supplying Party to object to such production before any production takes place.

20. If a Receiving Party learns of any unauthorized disclosure of Confidential Information, it shall take reasonable efforts to immediately (a) inform the Supplying Party in writing of such disclosure, including to whom the material was disclosed; (b) make a reasonable effort to retrieve all copies of the Confidential Information only to the extent the Receiving Party has control over the unauthorized disclosed documents; (c) and to the extent the Receiving party has control over the person or persons to whom unauthorized disclosures were made, inform the persons of the terms of this Protective Order.

V. Changes In and Objections to Designation of Information

21. **Inadvertent Disclosure of Confidential Information**. If a Supplying Party through inadvertence produces any documents containing Confidential Information without designating the documents as such in accordance with Paragraph 6 of this Protective Order, such inadvertence does not waive any claim for confidentiality that the Supplying Party may possess so long as the Supplying Party notifies the Receiving Party of the Confidential Information designation in writing within twenty (20) days of the date that the Supplying Party became aware or reasonably should have become aware of the failure to designate the information as Confidential Information. If a Supplying Party fails to designate information as Confidential Information within this twenty (20) day period, the Supplying Party waives its right to designate the documents as Confidential Information. The Supplying Party shall also supply the Receiving Party with a new copy of the documents designated in accordance with Paragraph 6 of this Protective Order,

which shall be substituted for the undesignated documents. Upon receipt of the substitute documents, the Supplying Party shall promptly return or destroy the improperly-designated document(s). Upon receipt of the Supplying Party's notice of the inadvertent disclosure, the Receiving Party shall, within a reasonable time, not exceed twenty (20) days, (a) treat such material in accordance with this Order; (b) take reasonable steps to notify any person to whom the Receiving Party disclosed such information of the new confidential designation; (c) take reasonable steps to procure the return of all copies of such material from any such persons who are not entitled to receipt of Confidential Information under the terms of this Protective Order ; (d) request in writing that such person procure the return of such information from any person to whom such person may have disclosed the information.

Notwithstanding the foregoing provisions of this section, the Supplying Party shall be deemed to have waived any claim of confidentiality with respect to the information inadvertently not claimed as confidential to which the Supplying Party fails to claim as Confidential Information, prior to sixty (60) days from the close of discovery.

22. **Challenges to Designation of Confidential Information**. A Receiving Party may challenge a Supplying Party's designation or redesignation by notifying the Supplying Party in writing that the confidentiality designation does not meet the definition of "Confidential Information". The designation by any party of Confidential Information raises no presumption that the information or documents are entitled under the law to protection. If any party contends, in writing, that any document, material, ESI, or other thing has been erroneously designated as Confidential Information, the party who designated the information as Confidential Information shall initiate a meet and confer within ten (10) days with the opposing party and the parties shall make a good faith effort to resolve issues relating to such designations. After the meet and confer, the party who designated the information as Confidential Information shall file a motion with the Court within thirty (30) days of receiving such written notification establishing that the information is entitled to protection as Confidential Information under the law. If the

designating party fails to timely file such a motion within the allotted thirty (30) day period, the document, ESI, material, or other thing, which is designated as Confidential Information, shall forthwith be produced and be deemed not to be Confidential Information. Any information or thing being challenged as inappropriately designated as Confidential Information shall nonetheless be treated as Confidential Information unless and until either (a) the designating party gives written permission to do otherwise, (b) the designating party fails to file a motion establishing that the challenged material is subject to protection as Confidential Information under the law within the thirty (30) day time period, or (c) the Court rules that the document, material, ESI, or other thing shall not be treated as confidential. Should the Court rule that any item designated as Confidential Information is not entitled to protection under the law, the designating party shall, within fourteen (14) days after all appeals are exhausted, provide the party challenging the confidential designation with copies of each item free of any language indicating that the item is subject to a Protective Order.

23. **Nothing in this Order shall be deemed to shift the burden of proof to the party challenging the confidential designation with regard to whether the materials produced pursuant to his Order are entitled to protection under the law as Confidential Information.**

VI. Filing Under Seal

24. **Where a Party Files Documents and Contends the Documents Should be Kept Sealed.** Where a party intends to file documents that contain Confidential Information with the Court, said party must file a motion for an order sealing the documents consistent with applicable law and comply with the provisions of Local Rule of Civil Procedure 5.6. A copy of the motion must be served on all parties that have appeared in the case.

25. **Where a Party Files Documents Claimed as Confidential by Another Party**. A party that files or intends to file with the Court Confidential Information

produced by another party but does not intend to request to have the records sealed, must do the following:

a. Make arrangements consistent with Local Rule of Civil Procedure 5.6 to lodge the documents under seal in accordance with local rules.

b. File redacted copies of the documents (if appropriate) so that they do not disclose the contents of the records that are subject to the confidentiality agreement or protective order;

c. Serve a copy of the motion on all parties that have appeared in the case; and

d. Give written notice to the party that produced the documents that the documents will be placed in the public court file unless the party files a timely motion to seal records.

If the party that produced the Confidential Information and was served with the above-mentioned notice fails to file a motion to seal the records within fifteen (15) days of receipt of the notice referenced in subsection 25(d) or to obtain a court order extending the time to file such motion, the clerk must promptly remove all the documents filed under seal pursuant to this provision from the envelope or container where they are located and place them in the public file. If the party files a motion or an application to seal within fifteen (15) days of receipt of the notice referenced in subsection 25(d) days or such later time as the Court has ordered, these documents are to remain conditionally under seal until the Court rules on the motion or application and thereafter are to be filed as ordered by the Court.

This section shall not apply with respect to documents admitted into evidence as exhibits at the trial of this matter. The Supplying Party reserves the right, however, to petition the Court for protection with respect to such documents admitted into evidence as exhibits at trial.

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VII. Miscellaneous Provisions

26. **Amending or Modifying Protective Order.** By written agreement of the parties, or upon motion and order of the Court, the terms of this Protective Order may be amended or modified. This Protective Order shall continue in force until amended or modified by consent or agreement of the parties or by order of the Court, and shall survive any final judgment or settlement in This Action, including but not limited to any final adjudication of any appeals petitions for extraordinary writs, unless otherwise vacated or modified by the Court. The Court shall have continuing jurisdiction over the terms and provisions of this Protective Order.

27. **After Final Adjudication**. Upon written demand by the Supplying Party made within thirty (30) days after final adjudication of This Action, including but not limited to, any final adjudication of any appeals and petitions for extraordinary writs, the Receiving Party shall assemble and return all Confidential Information to the Supplying Party or, alternatively, shall destroy all such material at the Supplying Party's expense. The Receiving Party shall verify the complete destruction or return to the Supplying Party all such Confidential Information by executing and mailing to counsel for the Supplying Party an Acknowledgment in the form attached hereto as **Exhibit B**. A copy of each such executed Acknowledgment shall be maintained by counsel for the Receiving Party and counsel for the Supplying Party. Notwithstanding the foregoing provisions of this paragraph, the Receiving Party may maintain its privileged communications, work product, Acknowledgments pursuant to the Protective Order, materials required to be retained pursuant to applicable law, and all court-filed documents even though they contain Confidential Information, but such materials shall remain subject to the terms of this Protective Order. This provision may not be invoked while the plaintiff's attorneys of record have active pending cases relating to IVC Filters manufactured by C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc.

28. The terms of this Protective Order do not preclude, limit, restrict, or otherwise apply to the use of Confidential Information at trial. The use of Confidential

Information during trial will be addressed in a later agreement between the parties, or, if they cannot reach an agreement, by further order of the Court.

29. Nothing in this Order shall be deemed a waiver of any parties' right to oppose any motion by any other party for a protective order or to oppose any objection to the disclosure of any information or documents on any legal grounds, including, but not limited to, the grounds that the party seeking the protective order has neither timely nor adequately objected to disclosure of such documents and information or moved for a protective order.

30. This Protective Order does not relieve any party of its obligations to respond to otherwise proper discovery in This Action. Nothing contained in this Order, or any action taken pursuant to it shall waive or impair any party's right to assert claims of privilege or work product protection, or the right of any party to object to the relevancy of admissibility of documents or information sought or produced into assert objections to requested discovery on grounds other than Confidential Information. This Protective Order also shall not affect or create any presumption with respect to the right of any party from seeking or obtaining additional protection with respect to any documents, materials, or information where allowed by law.

31. **Inadvertent Production.** Pursuant to Rule 502 of the Federal Rules of Evidence, inadvertent production of documents or electronically-stored information (hereinafter collectively "Inadvertently-Produced Documents") subject to work product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of immunity or privilege in the pending case or in any other federal or state proceeding. In the event that a party inadvertently produces documents or ESI subject to a claim of privilege, the Supplying Party shall, within 15 days of the discovery of the inadvertent disclosure, notify the other party in writing of the inadvertent disclosure. The Supplying Party may, in the notice, request a "clawback" of the inadvertently disclosed material. Upon receiving notice of the inadvertent production, the parties agree to follow the procedures provided by Federal Rules of Civil

Procedure 26 (b)(5)(B) respect to the clawback of the Inadvertently Produced Documents. All notes or other work product of the Receiving Party, reflecting the contents of such materials, shall be destroyed and not used.

If the party receiving such Inadvertently-Produced Documents moves the Court to dispute the claim of privilege or immunity, the party shall not assert the fact or circumstances of the inadvertent production to challenge whether the material is, in fact, privileged. Likewise, as part of any such motion, the Receiving Party shall not challenge the "reasonable steps", as described in Rule 502(b) of the Federal Rules of Evidence, taken or not taken by the Supplying Party.

Pursuant to Rule 502(d) of the Federal Rules of Evidence, there is no waiver of privilege or work product immunity in this matter or any other matter in any other jurisdiction for any document or ESI returned or destroyed under this subsection, or for the subject matter of any such document or ESI, whether the privileged document or ESI was inadvertently produced following review or as part of a "Quick Peek" production. In the event that either party receives information produced in discovery from the other party that reasonably appears to be Inadvertently-Produced Documents, the Receiving Party shall promptly notify the Supplying Party in writing of the apparent inadvertent production.

32. Each party shall retain all rights and remedies available to it under the law for the enforcement of this Protective Order against anyone who violates it.

33. Nothing in this Protective Order shall be construed to prevent this Court from disclosing any facts the Court relies upon in making any findings or issuing any ruling, order, judgment, or decree.

34. Within thirty (30) days of any information that has been claimed as Confidential Information being de-designated or made publically available, the Supplying Party shall provide notice of the Confidential Information that has been de-designated and/or made publicly available. Such notice shall be made by identifying bates numbers or by other means such as identifying categories of information where the identification of

bates numbers are not possible or not feasible. Publically available includes documents that have been filed with any court or entered as an exhibit during trial not under seal, provided, however that the Supplying Party is not required to provide notice of de-designation with regard to such documents until any motion or request to seal those documents is denied. This paragraph only applies to the extent that the Supplying Party knew or should have known that the information claimed as Confidential Information was de-designated or made publically available.

Dated this 9th day of November, 2015.

David G. Campbell
United States District Judge

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **AGREEMENT TO MAINTAIN CONFIDENTIALITY**

I, _____ (Name), have been given and have read a copy of the Protective Order, dated _____, 2015 in the case of MDL No. 2641, pending in the United States District Court District of Arizona. I understand and will strictly adhere to the contents of said Order. I understand that produced material disclosed to me is subject to the Order of this Court and that I am prohibited from copying, disclosing or otherwise using such material except as provided by said court Order. I understand that my unauthorized disclosure of any "Confidential Information" may constitute contempt of court and I agree to be personally subject to the jurisdiction of this Court for the purpose of enforcing my obligations under this Agreement, the Order, and any contempt proceeding that may be instituted for my violation of the terms of this Acknowledgment and the Protective Order. I also understand that my signature on this "Agreement to Maintain Confidentiality", indicating my agreement to be bound by the terms of this Protective Order, is required before I may be allowed to receive and review any produced document and materials that are designated as "Confidential Information" .

Date: _____ Print Signature:_____

Signature:_____

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **ACKNOWLEDGEMENT OF DESTRUCTION OR RETURN OF CONFIDENTIAL INFORMATION**

I, _____ (Name), am over the age of 18 years and am a resident of _____ County, _____. I make this Declaration based upon my personal knowledge, and I am competent to testify to the matters stated herein.

I have requested and received from _____ all of the "Confidential Information" contained in materials, transcripts, and other things within the scope of this Protective Order and produced in this case MDL No. 2641, pending in the United States District Court District of Arizona.

I have either destroyed or have attached hereto all of the "Confidential Information" contained in the materials, transcripts, and other things within the scope of this Protective Order including those materials which were returned to me by the experts and consultants mentioned above in accordance with the preceding paragraph, and as described in the Protective Order related to this matter. Notwithstanding the foregoing provisions of this paragraph, the Receiving Party may maintain its privileged communications, work product, Acknowledgments pursuant to the Protective Order, materials required to be retained pursuant to the applicable law, and all court-filed documents even though they contain "Confidential Information," but such materials shall remain subject to the terms of this Protective Order.

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/ / /

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ Print Signature:_____

Signature:_____

EXHIBIT C

[PHILLIPS ORDER ON MOTION TO SEAL, 6.1.15]

EXHIBIT D

G1A Recovery Filter Femoral System Design Verification and Validation Report

ETR 05-02-05

BARD

APPROVAL FORM

Form

FM0332100
Revision 2
Page 1 of 1

Check one X Validation

o Installation Qualification o Operational Qualification o Performance Qualification

o Engineering Test

Check one o Protocol X Report

Status: + Accepted o Rejected

Title G1A Recovery Filter Femoral System Design Verification and Validation Report

(Project #8027)

Product Line: Filters Number ETR 05-02-05 Revision: 0

To Be completed by Documentation: Effective Date: 02/24/05

Product/Process Affected: Filters

ORIGINAL

This document prepared in compliance with:

o SOPN0700040 Rev.
SOPE0700020 Rev
SOPI0193500 Rev
X SOPN0700090 Rev. 3
o SOPQ0157900 Rev.
o _____ Rev

Recommendation(s) have been entered into the database o
(If recommendations have been made, and this box is not checked, document cannot be released)

No recommendations were made +

TITLE	PRINTED NAME	SIGNATURE	DATE
Originator	David Micky Graves		2/24/05
Engineering	Andre Chanduszko	A. Chanduszko	2/24/05
Quality	Brian Hudson		2.24.05
Data Verifier*	Karen Lewis		2-24-05
Regulatory*	Karen Hutchison		2/25/05
Microbiologist*	N/A	N/A	N/A
Other*	N/A	N/A	N/A

*If applicable – reference applicable SOP for approval requirements.
Reference SOPN0700040, SOPN0700090, SOPE0700020, SOPQ0157900, SOPI0193500, or other relevant specification.

BARD
PERIPHERAL
VASCULAR

ETR-05-02-05
REV 0

G1A Recovery Filter Femoral System
Design Verification and Validation Report

Project # 8027

1.0 OBJECTIVE / PURPOSE OF TEST

The objective of this study was to verify and validate the design of the G1A Recovery Filter Femoral System (RF-210F), project # 8027. Design verification testing consisted of the following: dimensional, tensile, leak, marker band security, migration resistance, removal force, fatigue, and radial strength testing. Design validation testing consisted of evaluating the performance of the entire system, utilizing a simulated use anatomical model (ref. ETR-05-01-07). A chronic (TPR-04-09-11) and acute (ETR-05-01-05) animal study were also performed as part of design validation.

NOTE: Simulated Use testing consists of the following elements: Trackability, Pushability, Flex/Kink, Filter Advancement, Deployment Force, Deployment Accuracy, Filter Fixation, Ability to Deploy, and Deployment Configuration.

2.0 INTRODUCTION / BACKGROUND

The Recovery Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation with minimal trauma to the IVC. The Recovery Filter may be used as a permanent filter or be implanted temporarily to treat a temporary risk of pulmonary embolism.

The G1A Recovery Filter (RF-210F) has been modified, in comparison to the current Recovery Filter (RF-048F), to increase migration and fracture resistance, and to minimize the likelihood of leg twisting, appendage snagging, filter tilting, and caval perforation. These changes include an increased ground wire diameter of the hook from 0.0085" to 0.0105" in order to improve the fracture resistance of the hook and to improve the migration resistance of the filter. The leg span has been increased from 32mm to 40mm in order to improve the ability of the filter to expand with a distending vena cava. The total filter arm length has increased from 20mm to 25mm, enlarging the filter arm span from 30mm to 33mm to aid in filter centering. An additional inward bend has been applied to the end of the filter arm in order to improve arm interaction with the vessel wall, to address caval perforations and appendage snagging. The arc of filter arm, as it attaches to the sleeve, has been modified to have a smooth radiused transition instead of sharp angle. This change was made in order to reduce the stress concentration generated by the sharp angle and thus improve fracture resistance in the area of the filter.

Currently, the Recovery Filter (RF-048F) is deployed via a femoral vein approach using a delivery sheath with the filter mounted on a pusher wire. The new delivery system has been modified to increase the delivery sheath distal tip ID (including the distal marker band) from 0.083 +/-0.001" to 0.085+0.002"/-0.000" to allow for ease of delivery of the G1A filter. In addition to the change in sheath tip ID, the OD of the dilator shaft was increased from .079" to .081" to ensure a smooth transition in profile during sheath advancement into the anatomy. Additionally, the mounting spline of the pusher wire has been modified to accommodate the stronger hooks and assist the G1A filter deployment.

The G1A Recovery Filter Femoral System (catalog # RF-210F) consists of a dilator, a 7 French I.D. introducer sheath, and a delivery catheter. The G1A Recovery Filter is preloaded within the storage tube of the delivery system, which consists of pusher pad and spline attached to a

pusher wire and handle. The Femoral System is packaged in kits. Kit A consists of a dilator and a 7 French introducer sheath. Kit B consists of the delivery system containing the filter placed within a shipping tray. Each Kit is packaged in a separate unit pouch. Both unit pouches are packaged in a final unit pouch.

3.0 REFERENCE DOCUMENTS

3.1 TPR-05-01-13: G1A Recovery Filter Femoral System Design Verification and Validation Protocol
3.2 TPR-04-09-11: Chronic Animal Study Protocol
3.3 ETR-05-02-11: Chronic Animal Study Report *(last report pending)*
3.4 ETR-05-01-07: Validation of the Farlow Scientific Inc. Venous Anatomical Model
3.5 ETR-05-01-08: G1A Recovery Filter Femoral System Feasibility Test Report
3.6 ETR-05-01-06: G1A Recovery Filter Femoral System Acute Animal Study Report
3.7 ETR-04-12-15: G1A Recovery Filter Feasibility with Jugular/Subclavian System
3.8 ETR-04-10-04: G1A Recovery Filter (0.0105" x 0.060") Feasibility Phase 1
3.9 ETR-04-10-21: Removable G1A Filter, (Preliminary) Acute Animal Study
3.10 ETR-04-08-04: Recovery Filter (RF) Arm Fatigue Test Report (Feasibility Study)
3.11 ETR-04-06-06: Recovery Filter (RF) Migration Resistance Improvement DOE and Hook Radius Change (Feasibility Study)
3.12 TM1133300: Delivery System Component Tensile Test Method
3.13 TM1133400: Catheter Leakage Test Method
3.14 TM1133100: Vena Cava Filter Deployment Force Test Method
3.15 TM1133600: Delivery System Simulated Use Test Method
3.16 TM1134800: Migration Resistance
3.17 TM1135200: Filter Deployment Force Test
3.18 TM1132600: Post Sterile Dimensional Filter Testing
3.19 TM1132700: IVC Filter Radial Force Method
3.20 TM1134800: Filter Migration Resistance Testing
3.21 TM1133800: Recovery Filter Arm Fatigue Test
3.22 TM1132900: Recovery Filter Removal Force Test Method
3.23 TM1133300: Delivery System Component Tensile Testing
3.24 TM1133400: Catheter Leakage Test Method
3.25 TM1132600: Filter Dimensional Test
3.26 TM25001164: Band/Immobile Tensile Test *(GFO Test Method)*
3.27 RNF Fact Book #7081, Volume 1 of 13, Section 3, p 3 of 4
3.28 R5530435 BOM/Routing Process Report *(Preliminary DMR)*
3.29 RA070025: Risk Assessment of the G1A Recovery Filter Femoral System
3.30 DFMEA070022: Design Failure Mode and Effects Analysis of the G1A Recovery Filter Femoral System
3.31 PPS070028: G1A Recovery Filter Femoral System PPS

4.0 TEST PROCEDURE

All samples were sent to Covington, GA for 2x EO (cycle 7) sterilization.

Thereafter, all samples were environmentally stressed using the following procedures outlined in TM0635 (Covington document).

- Performed accelerated age testing at 62.8 °C for 24 hours per section 6.2 in TM0635
- Performed environmental stress conditioning for 24 hours per section 6.3.3 in TM0635.
- Allowed product to stabilize at room temperature for 24 hours (not outlined in TM0635).
- Performed ship testing on all samples per TM0058.

Reference Appendix 12.1 for the DV&V Protocol that displays the test procedure details and order of testing.

5.0 TEST MATERIALS

Test units were from the following lots:

- G1A total units 136
  - 35 units from Lot 01-05-024
  - 33 units from Lot 01-05-025
  - 35 units from Lot 01-05-026
  - 33 units from Lot 01-05-027
- SNF total units 119
  - 30 units from Lot GFOL3376
  - 90 units from Lot GFOL3377
  - 20 units from Lot GFOL0112
- RNF total units 60
  - 40 units from Lot GFOL2722
  - 20 units from Lot GFOJ0984

6.0 DEVIATIONS / EXCEPTIONS TO TEST PROTOCOL

6.1 The data for some test results were found to be non-normally distributed. These results were treated as attribute data or further evaluated using Weibull Regression Analysis. Details of the data analysis for each test are found in section 7.0 Test Results.

6.3 Migration Resistance @ 32mm - There was only one data point obtained for the SNF 32mm migration resistance when testing the first 30 filters. An additional 9 SNF filters were tested from a new lot of filters to achieve a total of 5 data points for 32mm SNF migration resistance. The 9 additional units were from a lot that was exposed to only one sterilization cycle. Therefore, these 9 units deviate from the specified 2x EtO, ship simulation and storage thermal cycle simulation. Additional RNF units were tested for migration in the 32mm simulated IVC for comparative analysis. These RNF units were not specified in the protocol. The additional RNF and SNF units were tested with clots

made from the large ID sausage casing, whereas the initial filters were tested with clots made from the small ID sausage casing.

6.4 The post sterile distal and proximal marker band OD measurements were specified in the protocol to be analyzed separately as variable data. Due to the similarities in the device design, non-normality of the data, sample sizes and the same specification, the post sterile distal and proximal marker band OD measurements were pooled and used as attribute data.

6.5 The pre-sterile spine OD measurements were specified in the protocol to be analyzed as variable data. Due to the non-normality of the data and sample sizes, the pre-sterile spline OD measurements could not be analyzed as variable data. The spline is made of stainless steel and is unchanged by the sterilization cycle. Therefore, an additional 60 spline OD measurements were taken post sterile and used as attribute data in place of the pre-sterile data.

6.6 One pair of filter arms from Lot#12-04-038 was found to have an arm span dimension of 35.5mm during the manufacturing pre-sterile inspection. This single data point exceeds the specification (maximum of 35mm). The filter was not scrapped by the operator as specified in the inspection procedure IPG625 and was included as one of the samples used in the DV&V testing. The Failure Investigation Report (see Appendix 12.5) found the root cause of this failure to scrap the filter to be operator error. The corrective action taken was re-training the operator stressing the importance of documenting and scrapping rejects.

The out of specification filter was not marked or labeled. It is uncertain as to the DV&V testing for which this filter was used. Therefore, the effect of a filter with one pair of arms that is .5mm over the specification was considered for the following tests.

- Bench Deployment Simulated Testing – Filter deployment configuration and filter centering may be affected by an out of specification arm span.
- Deployment Force Testing – The force required to deploy the filter, filter deployment configuration and filter centering may be affected by an out of specification arm span.
- Post Deployment Arm Span Dimension - The dimension of the filter after deployment may be affected by an out of specification arm span.
- Migration Resistance Testing – The ability of the filter to resist migration may be affected by an out of specification arm span.
- Filter Removal Force Testing - The force to remove the filter may be affected by an out of specification arm span.

There were no outliers found in the testing described above. Therefore, it is concluded that this deviation had no effect on the test data.

6.7 One pair of filter legs from Lot#12-04-038 was found to have a leg span dimension of 43.0mm during the manufacturing pre-sterile inspection. This exceeds the specification maximum of 42.0mm. The filter was not scrapped by the operator as specified in the inspection procedure IPG625, and was included as one of the samples used in the DV&V testing. The Failure Investigation Report (see Appendix 12.5) found the root cause of this failure to scrap the filter to be operator error. The corrective action taken

was re-training the operator stressing the importance of documenting and scrapping rejects.

The out of specification filter was not marked or labeled. It is uncertain as to the DV&V testing for which this filter was used. Therefore, the effect of a filter with one pair of legs that is 1mm over the specification was considered for the following tests:

- Bench Deployment Simulated Testing – Filter deployment configuration and filter centering may be affected by an out of specification leg span.
- Deployment Force Testing – The force required to deploy the filter, filter deployment configuration and filter centering may be affected by an out of specification leg span.
- Post Deployment Leg Span Dimension - The dimension of the filter after deployment may be affected by an out of specification leg span.
- Filter Leg Radial Strength Testing – The radial force of the filter may be affected by an out of specification leg span.
- Migration Resistance Testing – The ability of the filter to resist migration may be affected by an out of specification leg span
- Filter Removal Force Testing - The force to remove the filter may be affected by an out of specification leg span.

There were no outliers found in the testing described above. Therefore, it is concluded that this deviation had no effect on the test data.

6.8 The rating scale of 1-4 for simulated use testing as specified in the protocol was in reverse order from the rating scale of TM1133600. The rating scale defined in the protocol was used for the testing. All units tested were rated as acceptable or better.

6.9 The distal marker band OD, proximal marker band OD and dilator OD measurements were taken from units 1-30 instead of units 61-90 as specified by the protocol. This deviation was made in order to test efficiently by measuring the units that were available at the time. There were no anticipated differences in units 1-30 and 61-90 for these dimensions.

6.10 The G1A units for this study were specified in the protocol to be representative of the commercial product. The G1A units for this study were not packaged with an IFU as will be the commercial product. However, the packaging for this product is the same as that of the RNF. The RNF has successfully completed a packaging validation that provided evidence that the product was protected from damage and remained sterile after 2x EtO, ship simulation and storage thermal cycle simulation. Therefore, it is concluded that this deviation had no effect on the test data.

7.0 TEST RESULTS / SUMMARY OF DATA

NOTE: Raw data, summary statistics and normality testing can be found in the appendices (12.2 through 12.4)

7.1 Pre-Sterile Dimensional/Visual Inspection Test Results

Table 1. Pre-Sterile Dimensions measured at Glens Falls (Normal Data evaluated as Variable)

Component	Qty. Measured	Qty. Scrapped	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	LSL 95/95	USL 95/95	Result
Dilator OD (in)	53	0	0.081	0.0006	0.079	0.082	0.081 +.002 -.002	0.079	0.082	Pass

NOTE: The sample population was normal (p-value ≥ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level.

Table 2. Pre-Sterile Dimensions measured at Glens Falls (Non-Normal Data evaluated as Attribute)

Component	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	Result
Filter Arm Span (mm)	438	34	0.7	30	35	30-35	Pass
Filter Leg Span (mm)	438	41	0.5	39	42	38-42	Pass
Ground Wire OD (in)	100	0.0105	0.0001	0.0103	0.0107	0.0105 +.0005 -.0005	Pass
Filter Arm Length (mm)	876	18.62	0.310	17.79	19.57	18.75 +1.00 -1.00	Pass
Swaged Distal Marker OD (in)	140	0.120	0.0004	0.118	0.120	0.118 +.002 -.002	Pass
Swaged Proximal Marker OD (in)	140	0.120	0.0002	0.119	0.120	0.118 +.002 -.002	Pass

NOTE: The sample populations in Table 2 were non-normal (p-value < 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level. Therefore, the results were treated as attribute data. The individual measurements met the 95% confidence and 95% reliability attribute specification of 59 samples minimum with no failures

Table 3. Pre-Sterile Dimensions measured at Glens Falls (Non-Normal Data evaluated as Attribute)

Component	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	Result
Pre-Sterile Spline OD (in)	33	0.081	0.0005	0.080	0.081	0.081 +.001 -.001	Insufficient Sample Size*
Post Sterile Spline OD Over Slotted Area (in)	60	0.080	0.0005	0.080	0.081	0.081 +.001 -.001	Pass
Post Sterile Spline OD At Stop Area (in)	60	0.081	0.0002	0.080	0.081	0.081 +.001 -.001	Pass

NOTE*: The sample population for pre-sterile spline OD was non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks 'W' statistic at the 95% confidence level. There were an insufficient number of samples to evaluate the pre-sterile OD data as attribute data (95/95). Therefore, an additional 60 OD measurements were taken for both ends of the spline. These were taken post sterile and used as attribute data in place of the pre-sterile data. All individual measurements met the 95% confidence and 95% reliability attribute specification of 59 samples minimum with no failures. (See deviation section 5.5 for further details)

Table 4. Pre-Sterile Dimensional/Visual Test Results performed at Glens Falls (Attribute Data)

Component	Qty Measured	Qty Scrapped	Acceptance Criteria	Result (Post-Scrap)
Hook Dimensions	900	1	Must meet visual inspection Template TA-6004-1024	Pass
Introducer Sheath Tip ID	200	0	Sheath Tip must accept a 0.094" OD plus pin gage	Pass
Swaged Distal Marker ID (0.083" Pin Must Fit)	70	0	Sheath Tip must accept a 0.083" OD minus pin gage	Pass
Swaged Proximal Marker ID (0.083" Pin Must Fit)	70	1	Sheath Tip must accept a 0.083" OD minus pin gage.	Pass

NOTE: The units were measured during manufacturing at Glens Falls. Out of specification units were scrapped according to the manufacturing procedures.

7.2 Post-Sterile Dimensional/Visual Inspection Test Results

Table 5. Post-Sterile Dimensional Test Results (Reference Data)

Component	Qty. (n)	Mean	Std. Dev.	Min.	Max.
Filter Arm Span (mm) For Information Only	90	33	0.4	31	33
Filter Leg Span (mm) For Information Only	90	40	0.4	39	41

NOTE: This data was taken for informational purposes only. Therefore, there is no pass or fail criteria.

Table 6. Post-Sterile Dimensional Test Results
(Non-Normal Data Pooled and evaluated as Attribute)

Component	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	Result
Swaged Distal Marker OD (in)	30	0.120	0.0005	0.118	0.120	0.118 +.002 -.002	Insufficient sample size*
Swaged Proximal Marker OD (in)	30	0.120	0.0005	0.119	0.120	0.118 +.002 -.002	Insufficient sample size*
Pooled Swaged Distal & Proximal Marker OD (in)	60	0.120	0.0005	0.118	0.120	0.118 +.002 -.002	Pass

NOTE*: The sample populations for swaged distal and proximal marker OD were non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level. The distal and proximal marker band components are the same. The dimensions (ID/OD) of the sheath and mandrel over which the distal and proximal marker bands are swaged are also the same. Therefore, the results were pooled into one data set and treated as attribute data. The individual measurements met the 95% confidence and 95% reliability attribute specification of 59 samples minimum with no failures. (See deviation section 6.4 for further details)

Table 7. Post-Sterile Dimensional Test Results
(Non-Normal Data evaluated using Weibull Analysis)

Component	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	LSL 95/95	USL 95/95	Result
Dilator OD (in)	30	0.081	0.0007	0.080	0.082	0.081 +.002 -.002	0.080	0.082	Pass*

NOTE*: The Dilator OD sample population was non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level. The sample size of 30 measurements was insufficient to perform a Chi-Square Test. Therefore, the USL and LSL at 95% confidence and 95% reliability were calculated using a Weibull Analysis.

Table 8. Post-Sterile Dimensional/Visual Test Results
(Attribute Data)

Component	Qty. (n)	Acceptance Criteria	Result
Introducer Sheath Tip ID	60	Sheath Tip must accept a 0.085" OD minus pin gage	Pass
Swaged Distal Marker ID	60	Sheath Tip must accept a 0.083" OD minus pin gage	Pass
Swaged Proximal Marker ID	60	Sheath Tip must accept a 0.083" OD minus pin gage	Pass
Dilator ID	60	Sheath Tip must accept a 0.038" OD plus pin gage.	Pass
Spline/Filter Interaction	135	Filter hooks must not dislodge from spline during shipping or handling.	Pass

7.3 Bench Top Simulated Use Test Results

Rating Scale:
4 = Excellent/Exceptional
3 = Good
2 = Acceptable
1 = Unacceptable

Table 9. Bench Top Simulated Use Test Results
(Attribute Data)

Performance Requirement	Qty. (n)	PPS Specification	Acceptance Criteria	Result
Kink Resistance Sheath/Introducer	120	Sheath and Introducer must resist kinking and crushing.	Pass/Fail	Pass
Dilator Removal	120	The dilator must be able to be removed safely with minimal force.	Pass/Fail	Pass
Filter Compression Profile	120	The filter is deliverable through a 7 Fr ID introducer sheath.	Pass/Fail	Pass
Filter Advancement	120	The user must be able to advance the filter through the delivery system with a force rated acceptable.	Rating ≥ 2	Pass
Kink Resistance Pusher Rod	120	The pusher rod must resist kinking and crushing	Pass/Fail	Pass
Filter Deployment Accuracy	60	The user must be able to accurately deploy the filter.	(+ 10 mm of intended target)	Pass
Filter Centering	120	The filter sleeve must be at a minimum distancing of 1/3 the radius form the vessel wall.	Pass/Fail	Pass
Deployment Configuration	120	The filter must deploy with no arm or leg entanglement.	Pass/Fail	Pass

7.4 Deployment Force Test Results

Table 10. Delivery Peak Force Test Results
(Non-Normal Data evaluated as Attribute)

Performance Requirement	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	Result
Delivery Peak Force (lbf)	60	3.73	0.517	1.82	4.98	≤ 5	Pass

NOTE: The delivery peak force sample population in was non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level. Therefore, the delivery peak force measurements were treated as attribute data. The individual measurements met the 95% confidence and 95% reliability attribute specification of 59 samples minimum with no failures.

7.5 Filter Leg Radial Strength

Table 11 Filter Leg Radial Strength Test Results
(Non-Normal Data evaluated using W-Test Comparison of Medians at 95% Confidence)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
G1A Radial Force (grams)	30	4.5	0.23	3.6	4.8	G1A ≤ SNF	2.78E-11	Pass
SNF Radial Force (grams)	30	10.9	2.72	5.9	19.0			

NOTE: The sample populations were non-normal (p-value < 0.05) based on the Shapiro-Wilks test at the 95% confidence level. Therefore, Mann-Whitney W-Test was performed to compare medians at 95 % confidence level. The resulting p-value was below .05. Therefore, there is a statistically significant difference between the medians. The median of the SNF was greater than that of the G1A. Therefore, the result is a pass of the acceptance criteria.

7.6 Filter Removal Force

Table 12 Removal Peak Force Test Results
(Non-Normal Data evaluated using Weibull Analysis)

Performance Requirement	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	USL 95/95	Result
Removal Peak Force (lbf)	30	3.37	0.336	2.92	4.29	< 5	4.05	Pass

NOTE: The removal peak force sample population was non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level. The sample size of 30 measurements was insufficient to perform a Chi-Square Test. Therefore, the USL at 95% confidence and 95% reliability was calculated using a Weibull Analysis.

7.7 Marker Band Security Test Results

Table 13. Marker Band Security Test Results
(Attribute Data)

Component	Qty. (n)	Number of Bands that Moved	Acceptance Criteria	Result
Marker Band on Introducer Sheath	30	0	No movement	Pass

7.8 Tensile Strength Test Results

Table 14. Tensile Test Results & Capability Assessment (Non-Normal Data evaluated using Weibull Analysis)

Joint or Component	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	LSL 95/95	Result
Dilator to Hub Joint (lbf)	30	11	1.1	8	12	≥ 5	8	Pass*
Spline to Wire Joint (lbf)	30	41	13.1	24	62	≥ 5	20	Pass*

NOTE*: The both sample populations were non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level. The sample sizes of 30 measurements were insufficient to perform a Chi-Square Test. Therefore, the LSL at 95% confidence and 95% reliability were calculated using a Weibull Analysis.

7.9 Leakage Test Results

Table 15 Leakage Test Results (Attribute Data)

Joint or Component	Qty. (n)	No. of Leaks	Acceptance Criteria	Result
Dilator to Hub Joint	30	0	No leak	Pass

7.10 Filter Migration Test Results

7.10.1 15mm and 28mm Minimum Migration Resistance Pressure

Table 16 Combined 15mm & 28mm Filter Migration Resistance Test Results (Attribute Data)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	Result
G1A - 15mm Cavo (mmHg)	30	150 *	N/A	150 *	150 *	≥ 50	Pass
G1A - 28mm Cava (mmHg)	30	106.3	19.36	81.6	150 *	≥ 50	Pass
Combined G1A - 15mm Cava G1A - 28mm Cava (mmHg)	60	N/A	N/A	81.6	150 *	≥ 50	Pass

NOTE* The migration test equipment has an upper limit of 150mmHg. Therefore, the testing was stopped upon filters reaching 150 mmHg.

7.10.2 15mm IVC Migration Resistance Pressure

Table 17. 15mm Filter Migration Resistance Comparison of Variance (Non-Normal Data evaluated as Attribute)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
SNF - 15mm Cava (mmHg)	30	150	N/A	150	150	G1A filter must have equivalent or less variation as SNF	N/A	Pass
G1A - 15mm Cava (mmHg)	30	150	N/A	150	150			

NOTE: The migration test equipment has an upper limit of 150mmHg. Therefore, the testing was stopped upon filters reaching 150 mmHg. All filters reached the maximum value of 150 mmHg. Therefore, the F-test for migration results of the G1A and SNF could not be calculated but were deemed acceptable in a 15mm simulated IVC.

Table 18 15mm Filter Migration Resistance Comparison of Central Tendency (Non-Normal Data evaluated as Attribute)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
SNF - 15mm Cava (mmHg)	30	150	N/A	150	150	G1A filter must be statistically equivalent or greater than SNF	N/A	Pass
G1A - 15mm Cava (mmHg)	30	150	N/A	150	150			

NOTE: The migration test equipment has an upper limit of 150mmHg. Therefore, the testing was stopped upon filters reaching 150 mmHg. All filters reached the maximum value of 150 mmHg. Therefore, the T-test for migration results of the G1A and SNF could not be calculated but were deemed acceptable in a 15mm simulated IVC

7.10.3 28mm IVC

A number of SNF, G1A and RNF filters did not migrate (n=7, 11, and 4 respectively) due to clots passing the filters and therefore, inability to occlude the cava sufficiently. These data points were not included in the analysis. Additional filters were tested to produce total of 30 migration data points for each implant.

Table 19. 28mm Filter Migration Resistance Summary of Test Results (mmHg)

Filter Type	Number of Runs (n)	Mean	Std. Dev.	Min.	Max.
SNF	30	121.6	24.02	56.7	150
G1A	30	106.3	19.36	61.6	150
RNF	30	56.5	11.05	27.3	73.1

Table 20. 28mm Filter Migration Resistance Comparison of Variance (Non-Normal Data evaluated comparatively using Standard Deviations)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
SNF - 28mm Cava (mmHg)	30	121.6	24.02	56.7	150 *	G1A filter must have equivalent or less variation as SNF	N/A	Pass
G1A - 28mm Cava (mmHg)	30	106.3	19.36	81.6	150 *			

NOTE*: The migration test equipment has an upper limit of 150mmHg. Therefore, the testing was stopped upon filters reaching 150 mmHg. Some filters reached the maximum value of 150 mmHg. These data points were included in the statistical analysis even though they are truncated data. The data for SNF and G1A were found to be non-normal. Therefore, the F-test for migration results of the G1A and SNF could not be calculated. However, the standard deviation of the G1A filter was less than that of the SNF in a 28mm simulated IVC.

Table 21. 28mm Filter Migration Resistance Comparison of Central Tendency (Non-Normal Data evaluated using Mann-Whitney W-test of Medians)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
SNF - 28mm Cava (mmHg)	30	121.6	24.02	56.7	150 *	G1A filter must be statistically equivalent or greater than SNF	0046	Fail
G1A - 28mm Cava (mmHg)	30	106.3	19.36	81.6	150 *			

NOTE*: The migration test equipment has an upper limit of 150mmHg. These data points were included in the statistical analysis even though they are truncated data. The data for SNF and G1A were found to be non-normal (p-value < 0.05) based on the Shapiro Wilks W statistics at the 95% confidence level. The T-test for migration results of the G1A and SNF could not be calculated. Therefore, the Mann-Whitney W-test was performed to compare medians at the 95% confidence level. The resulting p-value was less than .05. Therefore, there is a statistically significant difference between the medians. The median of the SNF was greater than that of the G1A. Therefore, the result is a failure of the acceptance criteria.

Table 22. 28mm Filter Migration Resistance Comparison of Central Tendency (Non-Normal Data evaluated using Mann-Whitney W-test of Medians)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	p-value	Result
RNF - 28mm Cava (mmHg)	30	56.5	11.05	27.3	73.1	3.02E-11	G1A filter is statistically greater than RNF
G1A - 28mm Cava (mmHg)	30	106.3	19.36	81.6	150 *		

NOTE*: The migration test equipment has an upper limit of 150mmHg. Therefore, the testing was stopped upon filters reaching 150 mmHg. Some filters reached the maximum value of 150 mmHg. These data points were included in the statistical analysis even though they are truncated data. The data for RNF and G1A were found to be non-normal (p-value < 0.05) based on the Shapiro-Wilks W statistics at the 95% confidence level. The T-test for migration results of the G1A and RNF could not be calculated. Therefore, the Mann-Whitney W-test was performed to compare medians at the 95% confidence level. The resulting p-value was less than .05. Therefore, there is a statistically significant difference between the medians. The median of the G1A was greater than that of the RNF. Therefore, the result is a pass of the acceptance criteria.

7.10.4 32mm IVC

A number of SNF, G1A and RNF filters did not migrate (n=32, 26, and 2 respectively) due to clots passing the filters and therefore, inability to occlude the cava sufficiently. Additional filters were tested to produce total of 5 migration data points for each implant, so that a statistical comparison could be made

Table 23. 32mm Filter Migration Resistance Summary of Test Results (mmHg)

Filter Type	Number of Runs (n)	Mean	Std. Dev.	Min.	Max.
SNF	5	70.4	13.0	55.8	91.4
G1A	5	73.2	3.0	69.9	76.6
RNF	5	35.2	2.2	32.1	37.7

Table 24. 32mm Filter Migration Resistance Comparison of Central Tendency (Normal Data)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
SNF - 32mm Cava (mmHg)	5	70.4	13.0	55.8	91.4	G1A filter must be statistically equivalent or greater than SNF	.651	Pass
G1A - 32mm Cava (mmHg)	5	73.2	3.0	69.9	76.6			

NOTE: The data for SNF and G1A were found to be normal (p-value > 0.05) based on the Shapiro-Wilks W statistics at the 95% confidence level. The T-test (unequal variance) for migration results of the G1A and SNF resulted in a p-value greater than .05. Therefore, there is not a statistically significant difference between the two means. The mean of the G1A was greater than that of the RNF. Therefore, the result is a pass of the acceptance criteria.

Table 25. 32mm Filter Migration Resistance Comparison of Central Tendency (Normal Data)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	p-value	Result
RNF - 32mm Cava (mmHg)	5	35.2	2.2	32.1	37.7	1.52E-8	G1A filter is statistically greater than RNF
G1A - 32mm Cava (mmHg)	5	73.2	3.0	69.9	76.6		

NOTE: The data for RNF and G1A were found to be normal (p-value > 0.05) based on the Shapiro-Wilks W statistics at the 95% confidence level. The T-test (equal variance) for migration results of the G1A and RNF resulted in a p-value less than .05. Therefore, there is a statistically significant difference between the two means. The mean of the G1A was greater than that of the RNF. Therefore, the result is a pass of the acceptance criteria.

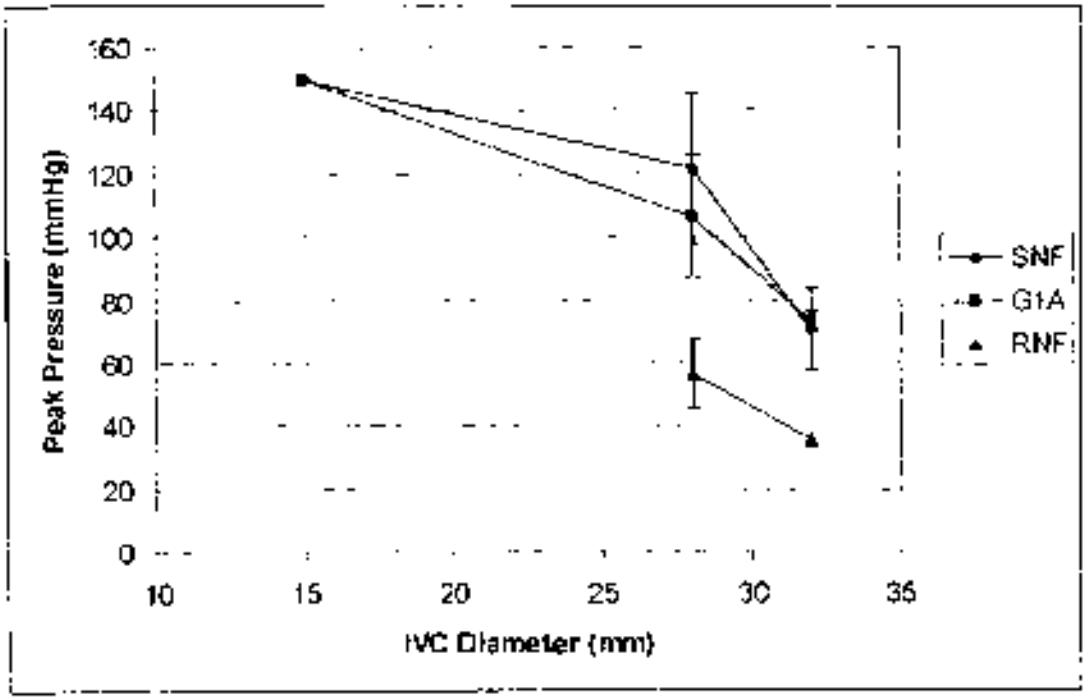


Figure 1. Filter Migration Resistance Summary.

7.11 Filter Arm Cyclic Fatigue Test Results

Table 27. Filter Arm Cyclic Fatigue Test Results (# Cycles to Failure)

Filter Type	Number of Samples (n)	Mean	Std. Dev.	Min.	Max.
RNF	30	51	13.6	29	90
G1A	30	606	106.5	350	850

NOTE: G1A sample population was normal (p-value > 0.05) and RNF sample population was non-normal (p-value ≤ 0.05) based on the Shapiro-Wilks W statistic at the 95% confidence level.

Table 28. Filter Arm Cyclic Fatigue Comparison of Central Tendency (Non-Normal Data evaluated using Mann-Whitney W-test of Medians)

Filter Type	Qty. (n)	Mean	Std. Dev.	Min.	Max.	Accept. Criteria	p-value	Result
RNF	30	51	13.6	29	90	G1A Filter must be statistically greater than RNF	0.000	Pass
G1A	30	606	106.5	350	850			

NOTE: The data for RNF was found to be non-normal (p-value < 0.05) based on the Shapiro-Wilks W statistics at the 95% confidence level. The T-test for fatigue results of the G1A and RNF could not be calculated. Therefore, the Mann-Whitney W-test was performed to compare medians at the 95% confidence level. The resulting p-value was less than .05. Therefore, there is a statistically significant difference between the medians. The median of the G1A was greater than that of the RNF. Therefore, the result is a pass of the acceptance criteria.

8.0 ANALYSIS OF DATA

Statistical analyses were performed using STATGRAPHICS *Plus*. Data sets were analyzed for normality using the following criteria. The Shapiro-Wilks W statistic at the 95% confidence level compared the quantiles of the fitted normal distribution to the quantiles of the data. The standardized skewness test evaluated lack of symmetry in the data. The standardized kurtosis test evaluated whether the distributional shape is either flatter or more peaked than the normal distribution.

Data found to be non-normally distributed by the Shapiro-Wilks W test was analyzed as attribute data when sufficient sample sizes were available. In the event of insufficient samples sizes to meet the minimum attribute sampling requirement, the data was analyzed for normality using the Chi-Square Test. Data found non-normal by the Chi-Square Test was evaluated using Weibull Regression Analysis. The Weibull analysis was used to calculate the 95% confidence and 95% reliability specification limits.

When comparative data sets were found to be non-normally distributed, a Mann-Whitney W test was used to compare the medians of the two samples. This was accomplished by combining the two samples, sorting the data from smallest to largest, and comparing the average ranks of the two samples in the combined data.

9.0 DISCUSSION OF RESULTS

The following acceptance criteria were met:

9.1 Pre-Sterile Dimensional/Visual Inspection Test Results

- Dilator ID
- Filter Arm Span
- Filter Leg Span
- Ground Wire OD
- Filter Arm Length
- Swaged Distal Marker OD
- Swaged Proximal Marker OD
- Spline OD
- Hook Dimensions
- Introducer Sheath Tip ID
- Swaged Distal Marker ID
- Swaged Proximal Marker ID

9.2 Post Sterile Dimensional/Visual Inspection Test Discussion

- Filter Arm and Leg Span
- Swaged Distal/Proximal Marker OD
- Dilator OD
- Introducer Sheath Tip ID
- Swaged Distal Marker ID

- Swaged Proximal Marker ID
- Dilator ID
- Spline/Filter Interaction

9.3 Bench Top Simulated Use Test Discussion

- Kink Resistance Sheath/Introducer
- Dilator Removal
- Filter Compression Profile
- Filter Advancement
- Kink Resistance Pusher Rod
- Filter Deployment Accuracy
- Filter Centering
- Deployment Configuration

9.4 Delivery Force Test

9.5 Filter Leg Radial Strength Test

9.6 Filter Removal Force Test

9.7 Marker Band Security Test Discussion

9.8 Tensile Strength Test Discussion

9.9 Leakage Test Discussion

9.10 Migration Resistance in 15 mm IVC
- G1A ≥ 50 mmHg

9.11 Migration Resistance in 28 mm IVC
- G1A Variance < SNF Variance
- G1A ≥ 50 mmHg

9.12 Migration Resistance in 32 mm IVC
- G1A ≥ SNF

9.13 Filter Arm Cyclic Fatigue Test

The following acceptance criteria could not be statistically analyzed:

9.14 Migration Resistance in 15 mm IVC
- G1A ≥ SNF:

All G1A and SNF filters reached the maximum value of 150 mmHg that the testing system could produce. Therefore, there is no way to determine statistical equivalency

between the filters or lack of thereof. The achieved peak pressures were three times higher than the minimum requirement of 50 mmHg based on the PPS.
Based on this data we determined that the performance of G1A was equivalent to SNF and G1A was able to withstand minimum of 50 mmHg pressure

9.15 Migration Resistance in 28 mm IVC

- G1A Variance ≤ SNF Variance:

The data for SNF and G1A were found to be non-normal. Therefore, the F-test for migration results of the G1A and SNF could not be calculated. However, the standard deviation of the G1A filter was less than that of the SNF in a 28mm simulated IVC.

The following acceptance criteria **were not met**:

9.16 Migration Resistance in 28 mm IVC

- G1A ≥ SNF

The data produced from this testing did not meet the acceptance criteria, as defined in the protocol/PPS. However, the G1A filter did significantly outperform the current RNF filter in the 28 mm IVC. Specifically, all G1A filters migrated at pressures in excess of 80 mmHg, whereas all RNF filters migrated at pressures below 80 mmHg. Additionally, when compared to previous competitive testing (ref. ETR 04-03-02), the G1A filter performed comparably or better than many of the competitor's filters.

10 CONCLUSION

The G1A Recovery Filter Femoral System met all of the acceptance criteria, as defined in PPS070028 and the protocol (TPR-05-01-13), with the exception of Migration Resistance being greater than or equal to that of the SNF at 28mm. While the G1A Recovery Filter (RF210F) did not meet this criterion, it did show significant improvement over the current Recovery Filter (RF048F). Specifically, all G1A filters migrated at pressures in excess of 80 mmHg, whereas all RNF filters migrated at pressures below 80 mmHg. Also, when compared to previous competitive device migration testing the G1A Recovery Filter performed at a comparable or higher level than most competitors' product. Therefore, the migration resistance acceptance criteria (at 28mm) may have been inappropriately established and in excess of the true goal of the Recovery G1A Fast Track project, which was to significantly improve the migration resistance of the Recovery filter. Taking this factor into consideration, the data presented in this report does support the goal of the project. Therefore, it is recommended that the PPS requirements for migration resistance be adjusted to more accurately match the goal of the project. Having taken this action, the data in this study may be used to support the regulatory submissions and ultimate commercialization of the G1A filter.

11 RECOMMENDATIONS

The G1A Recovery Filter Femoral System demonstrated acceptable performance in all tests except for migration resistance equivalence to SNF at 28mm. The G1A Recovery Filter demonstrated superior performance in migration resistance over the RNF. Therefore, the following changes to the PPS are recommended for the G1A Recovery Filter Femoral System.

Filter Migration Resistance, **Change From**:

User Requirement	Engineering Specification
Migration resistance of G1A must be statistically equivalent to or greater than that of the SNF filter.	Migration resistance of G1A in simulated IVC diameters of 15 mm and 28 mm must be statistically equivalent to or greater than that of SNF filter. Standard deviation of G1A results in simulated IVC diameters of 15 mm and 28 mm must be statistically equivalent to or smaller than that of SNF filter. G1A must withstand a minimum of 50 mmHg pressure in simulated IVC diameters of 15 mm and 28 mm.

Filter Migration Resistance, **Change To**:

User Requirement	Engineering Specification
Migration resistance of G1A must be statistically greater than that of the RNF filter in a 28mm diameter simulated IVC.	Migration resistance of G1A in a simulated IVC diameter of 28 mm must be statistically greater than that of RNF filter. G1A must withstand a minimum of 50 mmHg pressure in a simulated IVC diameter of 28 mm.

12 APPENDICIES

12.1 G1A Recovery Filter Femoral System DV&V Protocol
12.2 Manufacturing Documentation
12.3 Raw Test Data Recording Sheets
12.4 Statistical Analysis Data Sheets
12.5 Failure Investigation Report
12.6 Modified Recovery Filter Respiratory Fatigue Test - Rationale

EXHIBIT E

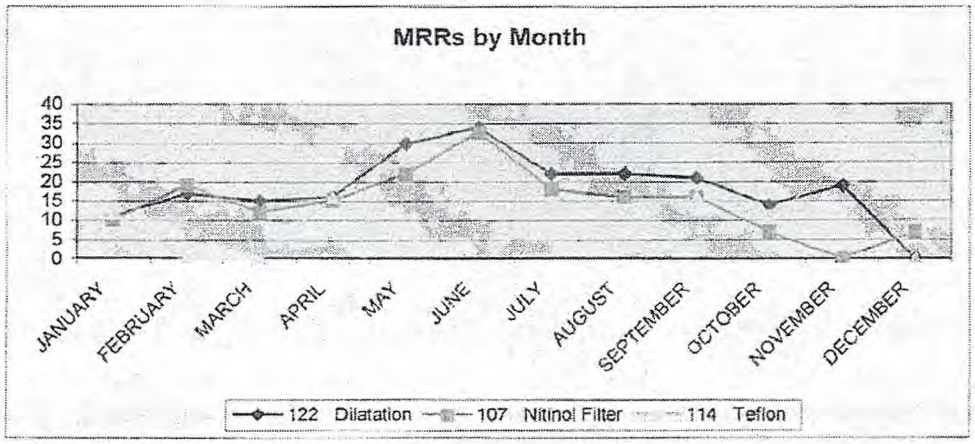
Memorandum

To: Peter Palermo
From: Kerry Chunko
Date: 01/31/05
Re: Quality Plan 2005

Purpose
To review plant quality indicators for 2004 and develop a plan for improvement for 2005.

Material Reject Reports

Dilatation and Filters initiated the largest number of MRRs, with a combined total of 396. This accounted for 23% of the plant total, down from 26% in 2004. This was followed by Teflon. Significant improvement in Filters occurred following checker sheet implementation in June.

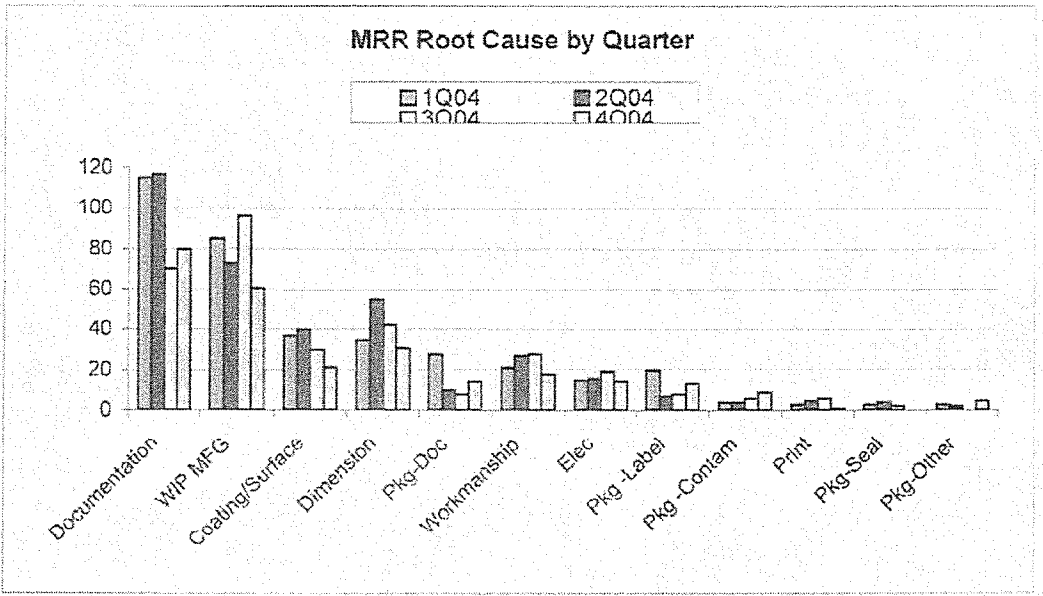


MRRs spiked in February following the implementation of the new LHR format, then steadily decreased every quarter:

EXHIBIT Schultz-5
Date: 1-30-14
M.L. GRAY, CSR, RPR

- 1Q04 476 +27%
- 2Q04 458 -4%
- 3Q04 427 -8%
- 4Q04 362 -18%

The primary root causes were Documentation (382), WIP (315), Dimension (163), Coating/Surface (128). Documentation increased 22% from 2004, root cause identified as new LHR format. WIP decreased 31% from 2004. Electrical decreased 59% dropping it from the third highest root cause 2003 to fifth in 2004. Improvements were seen throughout fourth quarter, with the notable exception of Package Label. However, package Label decreased 33% from 2003 totals.



Scrap

Total scrap dollars have tripled since JDE implementation. Root cause: Legacy system only included materials. JDE includes materials, labor and overhead. $7M scrap projected for 2005. Drivers are Conquest/Dilatation. Conquest scrap has tripled with volumes. Current improvement tactic to achieve 85% yields, 90% by year end. There is a large amount of scrap at final catheter for balloon issues not

discovered at the SA level. Implementing split molds to address pbax issues. Team is examining ways to inspect SAs fully inflated for cosmetic issues.

Complaints

Top product groups for complaints were Filters (207), Biliary (186), and Dilatation (135). Total complaint rate Jan – July driven by papillitomes, September – December driven by XT insertion/removal difficulties (reported from Germany), and Filter complaints. However, Filter complaint rate flat per 1000 units sold. XT complaint rate spiked in Sept, Oct and Nov. Returned to normal levels in December. No root cause identified for insertion/removal complaints.

The breakdown of the top groups are:

	Filters	Biliary	Dilatation
Complaints	207	186	135
Main Contributor	RNF Limb/hook breakage, migration	Tip/Wire Orientation	XT insertion/removal (49)
Corrective Action	RNF redesign G1A	Reviewed during Bard Corporate Audit	None - FI complete, no root cause determined
Result	Launch 2Q05	90% decrease in August 2004	Decrease in events
Action 2005	G1A	Off load to Conmed	XTG2

CAPA

Top 5 data sources: MRR (49), Complaints (15), Audits (14), Onload related(10), and Process (8). Change from 2003:

- MRR +23%
- Complaints +88%
- Audits -43%
- Onload 0
- Process -20%

MRR source driven by use as is dispositions with open preventive actions. Complaints driven by lengthy failure investigations for tip stock crazing, latent adhesive transfer, additional broken plunger post CAPA and open supplier corrective action requests.

Top 5 root causes: Documentation Related (25), Inadequate procedures (21), Supplier related (18), Procedural Deviation (14), Process System Improvements (12), Training related (11).

CAPA initiated from customer complaint source increased due to investigations involving outside laboratory testing and supplier corrective actions. Six CAPA were initiated due to supplier issues, seven initiated due to GFO process issues, one was found to be non-defective.

Department Code:	CAPA No:	Priority Level	Description:	Date Initiated:
Molding - 10478126	07-04-008	2	A review of complaint #'s 6103110037, 6103110055 and 6103110103 indicated difficulty at end use in placing a .035" guidewire through the port on Papillotome Product # 7104AC-apollo3 AC4.5F Shrt Taper.	1/23/2004
Quality Administration - 10479004	07-04-049	1	A customer complaint sample (Complaint file 11850) was forwarded to Glens Falls Complaints department and could no be located in order to complete the investigation.* Complaint Sample was later located in the complaint lab on 7/9/04	7/12/2004
Stinger - 10478119	07-04-051	2	Complaint File # 6138: During lot conversion process for Stingetr rework Item # 2100027SM lot 07EM1569 was converted to Item # 210007SM lot # 07BN4453	7/14/2004
Viking - 10478118	07-04-056	2	Complaint File: 15527 - Surelink Cable (560002A Lot GFOC0556)returned in the complaint system with deformation/slight melting of the #4 tail wire on the cable. Note that the Cable was functioning electri	8/18/2004
Conquest Balloons - 10478112	07-04-066	3	MRR# 36425 / Complaint Files 19785 [to include complaint 19324, 14675 No samples returned]Additional introducer passage testing for Conquest 8 mm balloon catheters	9/24/2004
Biliary/Endicinch - 10478129	07-04-069	2	Complaint # 20102: Manufacturing related complaint event (non-reportable).Customer complained of "Vacuum Leak", Complaint was confirmed.	9/29/2004
Steerables - 10478111	07-04-071	2	Complaint File: 20416: A second complaint has been reported on for a broken plunger on a push -pull style steerable catheter.	10/5/2004
Orbiter ST - 10478121	07-04-073	2	Complaint # 20788 Orbiter ST samples with greater than typical force required to initiate curve.	10/13/2004
1300's Mfg - 10478104	07-04-074	2	Tigertail catheter (Item 139005, Lot 07KN0467) Complaint for tip separation. Only the 8 mm black tip section was returned.	10/15/2004
Orbiter PV - 10478120	07-04-076	2	Complaint # 21433 - Complaint sample confirmed for adhesive transfer. The foam pad assembly lot (8978931) was not deemed as discrepant in previous investigation.	10/15/2004
Wovens - 10478102	07-04-081	2	Complaint File # 19369 Dual Lumen Ureteral Catheter (Item 130200 Lot # 07KN3517 confirmed complaint for Lumen will not accept .038" guidewire.	10/22/2004
Nitinol Filter - 10478107	07-04-083	2	Complaint File # 20755 Welding mandrel found to lodged in the lumen of RC 15 Recovery Catheter	10/26/2004
Modular Electrodes - 10478101	07-04-090	2	Customer Complaint # 26153 / 26163 Signal noise	11/15/2004
07-7864: Biliary/Endicinch - 10478129	07-04-104	1	MRR35270 Supplier: Alga Plastics During Sealing of Tyvek lids on tray PK5040003(Papillotome) an insufficient seal was found due to a high spot on the sealing flat.	12/30/2004

Top 5 departments:

- Regulatory Affairs (12) Includes internal system audits that were not tied to a specific departmental code
- Ports (11)
- Conquest (9)
- Machining (8)

- 7810 Nitinol Filter (8)

Breakdown of CAPA by department (does not include on-load open action items) is attached.

Contributing Factors:

- Use As Is MRRs with CAPA to track implementation of long term preventive actions.
- Documentation CAPA driven from the Internal Audit source. Mostly documentation incorrect or incomplete.
- Non-compliance to procedures could be attributed to the large population of new employees as demonstrated by the high percentage of training related root causes. 250 new employees attended orientation during 2004.
- Packaging CAPAs consisted of: 1) Manufacturing process with Supplier (Perfecseal Philidelphia, Prent, Alga, Brentwood), and 2) Handling process at GFO.

Action?

Supplier Management

143 MRRs were classified as supplier related out of 6,683 lots inspected resulting in a MRR rate of 2.1% to a goal of 2%. This was a significant decrease from 3.62% in 2003.

The top 5 suppliers by lots inspected:

1. Precious Metals Plating (324)
2. Contech (303)
3. Johnson Matthey (201)
4. Future Matrix Interventional (154)
5. Precision Interconnect (120)

The top 5 suppliers by MRR:

1. Precision Interconnect (12)
2. Precision Extrusion (8)
3. Epic (4)
4. Multiple suppliers at (2)

Major quality issues by Suppler:

- Perfecseal (slits/holes in pouches and misaligned seals)
  1. Root cause - roll handling/unwrapping at Perfecseal
  2. Corrective action - 100% sort of existing end items and unused pouches

3. Preventative action – Qualified Perfecseal OshKosh and transfered all business

- Brentwood (holes in trays)
  1. Root cause - lack of control of material at supplier
  2. Corrective action – 100% sort of existing end items and unused trays
  3. Preventive action – 1) implemented 100% inspection in manufacturing prior to traying product, 2) transfer business to Prent (target 2005)

- Prent (hole in tray)
  1. Root cause – Tool damage and improper set up verification
  2. Corrective action –100% sort of existing end items and unused trays
  3. Preventive action – Multiple improvements at supplier verified by a follow up audit

- Alga (insufficient seal on tray)
  1. Root cause – 1) Too much heat on flange at start up, 2) segregation of defects at start up
  2. Corrective action - 100% sort of existing end items and unused trays
  3. Preventive action – Retraining of operators on monitoring production start up and delaying die cutting operation until any/all forming defects are resolved.

Summary

QA projects continue to focus on cost reduction and inspection reduction/elimination.

MRR and scrap reduction should focus on Filters, Conquest, XT catheters and PV Loop. Conquest scrap has tripled with volumes. Current improvement tactic to achieve 85% yields, 90% by end of 2005. XT catheter improvements are outlined in the complaint section below. Implementation of manufacturing checker sheets had decreased MRRs in both Filters and Navarre.

Conquest scrap reduction tactic to continue in 2005:

- $136k destructive test reduction. Target 1Q05
- Split Die balloon flattening process implementation in 2 phases:
  1. 12x4 $20k - Target 3Q05
  2. 6,7,8x4 $123k – Target 4Q05

Complaints –

next Generation

1) RNF improvements with G1A Filter redesign.

- Filter modifications (hooks/arms)
- Modification of femoral delivery system (new spline cap)
- Compatible with standard snare, Superior Delivery System and Cone Glens Falls

Validation scheduled 1Q05 with launch 2Q05.

2) XT upgrade project was initiated to enhance the performance characteristics and manufacturability of the XT product line. This involves:

- Using a more stable material (Nylon 12 vs Nylon 11)
- Balloon cone angles will be reduced to alleviate introducer insertion/removal issues.
- The RBP of the balloons should increase making it a more robust balloon.
- Balloon neck sizes will become standardized to improve welding to shafts
- All balloons will be formed on the automated balloon machines (same as Conquest) which results in a more stable process.
- Shaft, tip and vent hole design may change to improve inflation (for stents) and deflation time.

We will begin receiving equipment 1Q05. Validation (OQ/PQ) scheduled for 2Q05. Target launch for the new product line is 3Q05.

CAPA –

1) Need to implement QA-STD-011 for all product/process transfers including design transfers.

2) Packaging upgrades continue:

- Replacing sealers which cannot produce seals conforming to the Corporate Sterile Packaging Standard.
- Redesigning the Stinger/Orbiter package to include rounded tray edges, more robust uncoated Tyvek, and a more robust carton. Implementation targeted 2Q05.

PMP Action plan

3) Need to strengthen CAPA verification of effectiveness measurement for compliance to ISO 13485:2003. Target 1Q05

Supplier Management -

7
6 1) Focus vendor audits on process controls and data integrity. Target 1Q05

2) Certified Suppliers - 25% of 2005 receipts on STS or certification

- 4 certification audits scheduled 2Q05 (6.5% of receipts; YTD = 19%)
- 2 certification audits scheduled 3Q05 (1%; YTD = 20%)
- 1 certification audit scheduled TBD (5%)

How? Plan

3) Incorporate ISO14971 Risk Management into supplier qualification process or onloading new RMs. Target 3Q05

4) Need to develop a tracking mechanism for Supplier Corrective action Requests. Target 1Q05 Who?

Inspection Reduction –

Total inspection reduction annualized hours = 16,000. Projects currently identified below:

Team	Description of project	Project Status	Project Leader	total annual savings (hours)
IQC	Certify Suppliers / reduce IQC inspection	80 hours implemented	Chapman	600
Nitinol IQC	Batch spools; test every third spool rec'd	not started yet	Baskerville	480
Gesco	Eliminate unwrap / rewrap portion of QC	CR being assembled	Lasky	720
Guidewires	Change to skip lot inspection	not started yet	Baskerville	960
Guidewires	Change to online IPG400	not started yet	Baskerville	600
Dilatation	Change to online QC inspect *	not started yet	Slavin	960
Machining	Change to C=0, IV 0.10 visual inspect	CR submitted on 9/15/04	TBD	600
Machining	Automate MPB066 100% inspect ports	determining feasibility	TBD	3600
Dilatation	Conquest destruct switiching rule	Implemented	Slavin	458
Dilatation	Weld pull test reduction, SPC startup	Implemented	Slavin	480
			TOTAL	8858

Details?

Lean Manufacturing –

1) 5s all QA/QC areas. Target 1Q05

2) Implement partial lot release throughout the plant. Target 2Q05

3) Implement skip-lot inspection for SAs. Target 2Q05

4) Implement in-process inspection. Target 3Q05

5) Optimize sterilization by transfer to Regional &/or optimizing current cycle. Target 4Q05

6) Apply Lean manufacturing to all major QA/QC processes
- QC Inspect - Target 2Q05
- Lot Release - Target 2Q05
- CR review/approval - Target 4Q05
- CAPA - Target 3Q05
- Complaints - Target 3Q05

EXHIBIT F

From: Wong, Natalie [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=NWONG]
Date: 10/1/2006 12:40:39 AM
To: De La Torre, Therese [Therese.DeLaTorre@crbard.com], Shamji, Imtiaz [Imtiaz.Shamji@crbard.com], Sorsher, Gary [Gary.Sorsher@crbard.com], Hudnall, Janet [Janet.Hudnall@crbard.com], Hudson, Brian [Brian.Hudson@crbard.com], Schulz, Gin [Gin.Schulz@crbard.com]
Subject: Fracture Docs
Attachments: DRAFT RNF Fracture 09-30-06.ppt, risk-benefit.doc, Natalie's Items for R002.doc, Steps For Calculating Estimated Rates.doc, Bard100.jpg

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Please see attached for:

* Draft Presentation - Only section that I need help on is the Pros and Cons for the "Potential Next Steps"
* Risk/Benefit document - it is draft format and I'm not sure how much detail we should put into it.
* My sections for R002. Note on the R002, Mike Terlizzi is on the sign-off for Marketing which is incorrect, should be Kevin Shifrin.
* Steps for Calculating the Estimated Rates

Please let me know if you need anything else.

Thanks,
Natalie

Recovery Filter (Gen 1) Fractures

Action Item Update

Privileged and Confidential

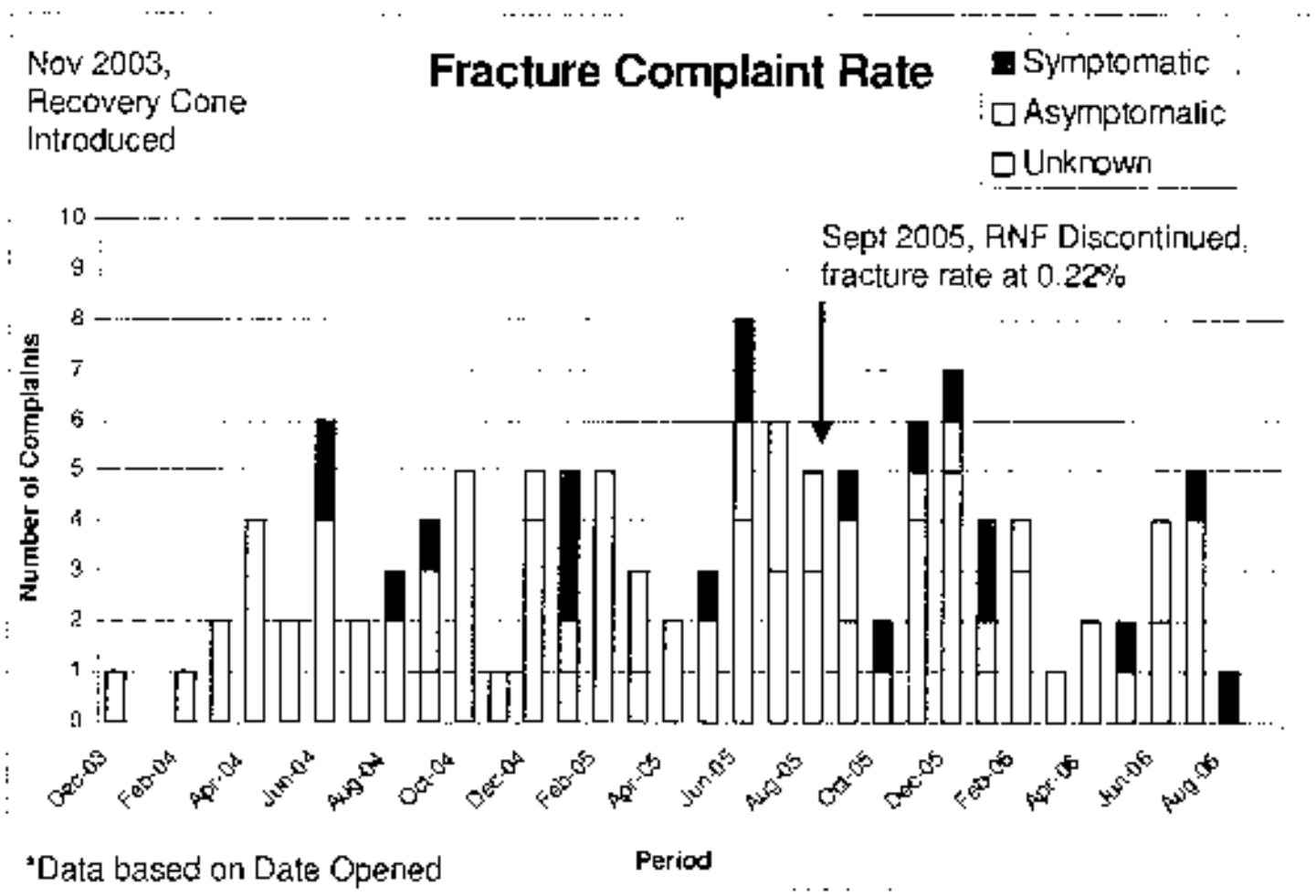
Recovery Fracture Summary

- Reporting Date Range: 12/2002 – 8/31/06
- Product Code: RF048F
- Summary of Complaints:

Information	*Total Qty*
Total No. of Units Distributed:	34,315
Total No. of Complaints:	116 (does not include 1 from [Redacted] Clinical Trial, Canada)
Complaint Rate:	**0.34%** → **SIR Guidelines* Fracture Rate is 2 - 10%**
Asymptomatic Rate:	0.28% (97/34,315)
Symptomatic Rate:	0.06% (19/34,315)

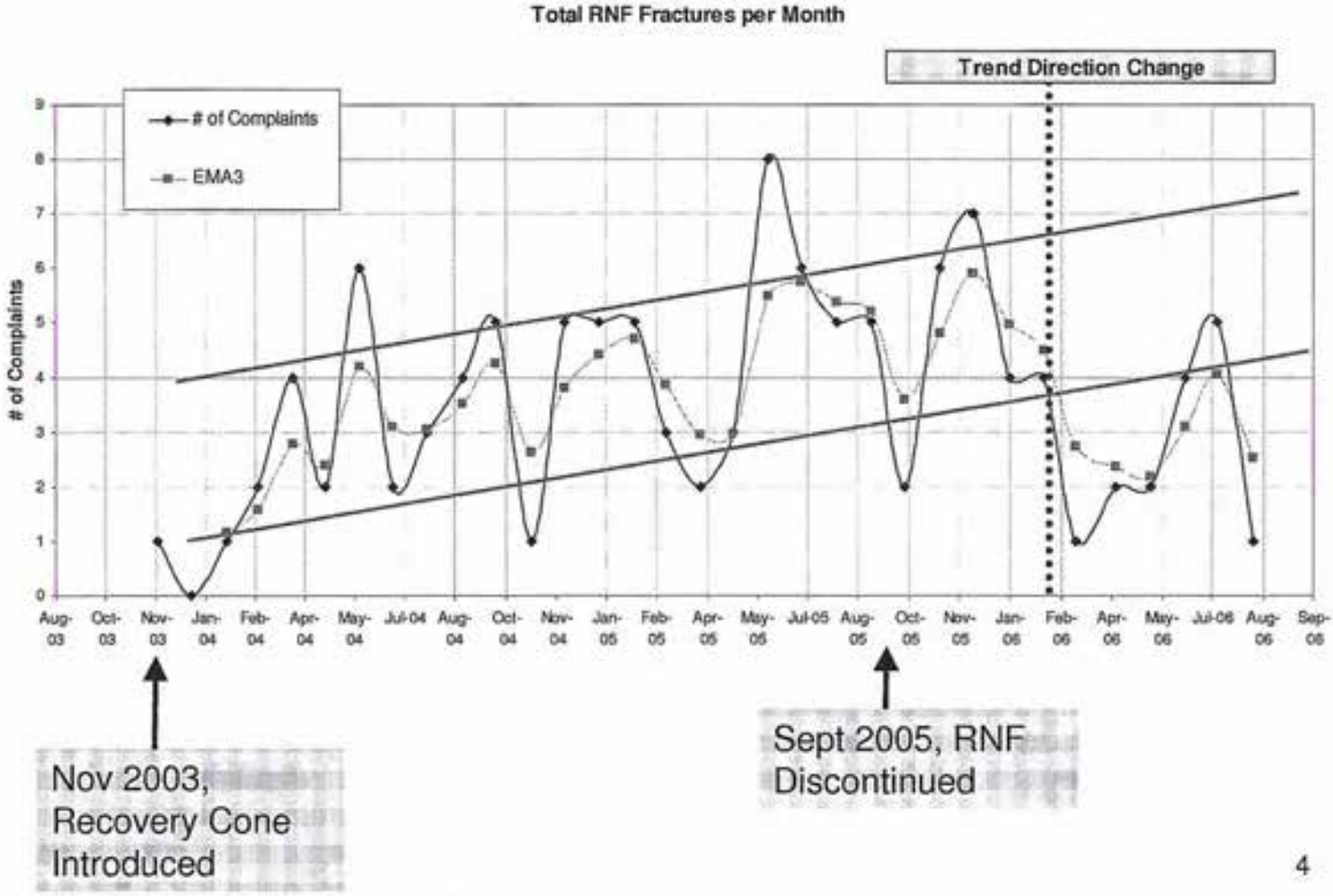
* Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. J Vasc Interv Radiol 2003; 14:S271-S275.

Recovery Complaint Trend



*Data based on Date Opened

Total RNF Fractures per Month



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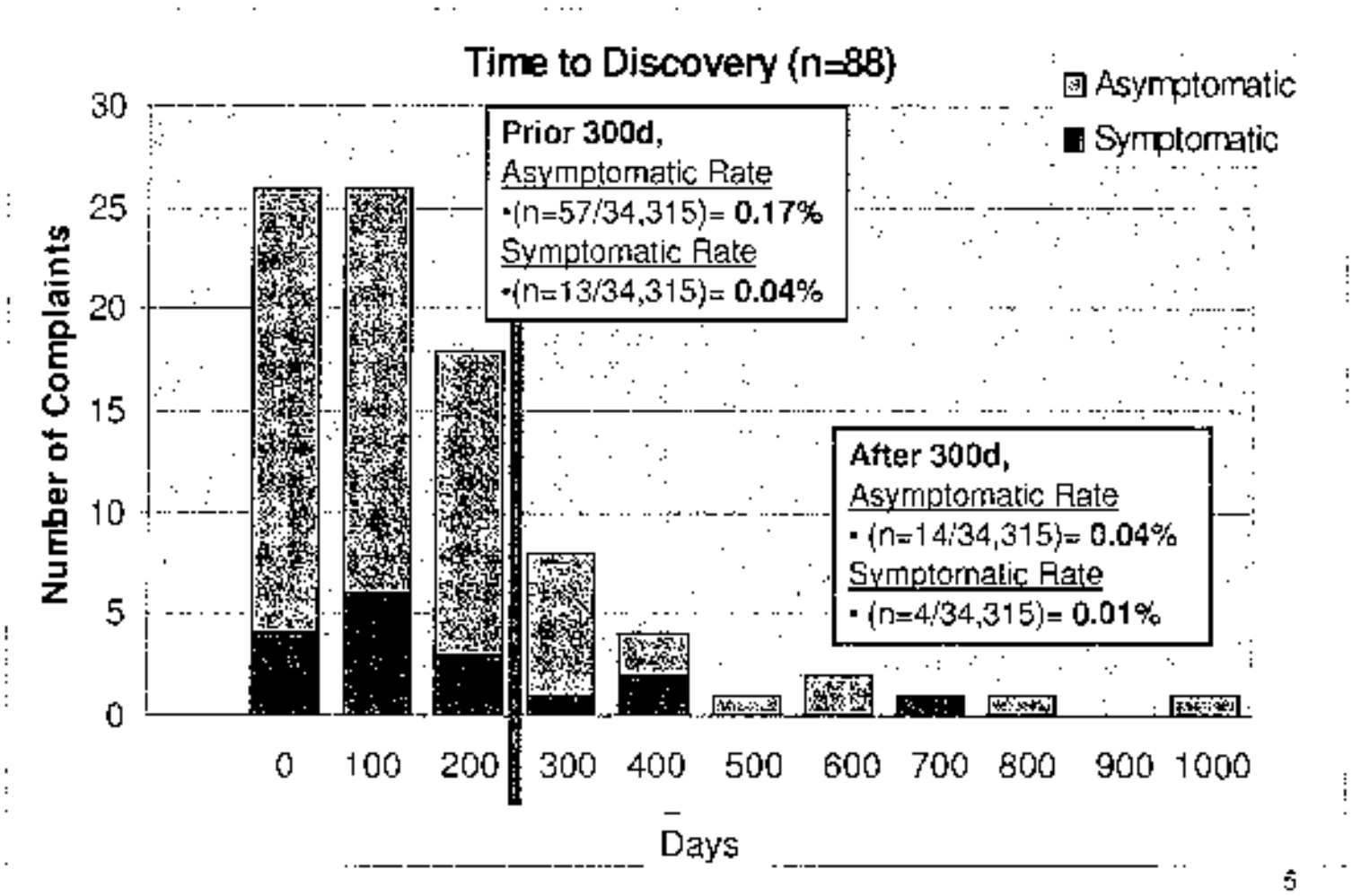
Recovery Time to Discovery



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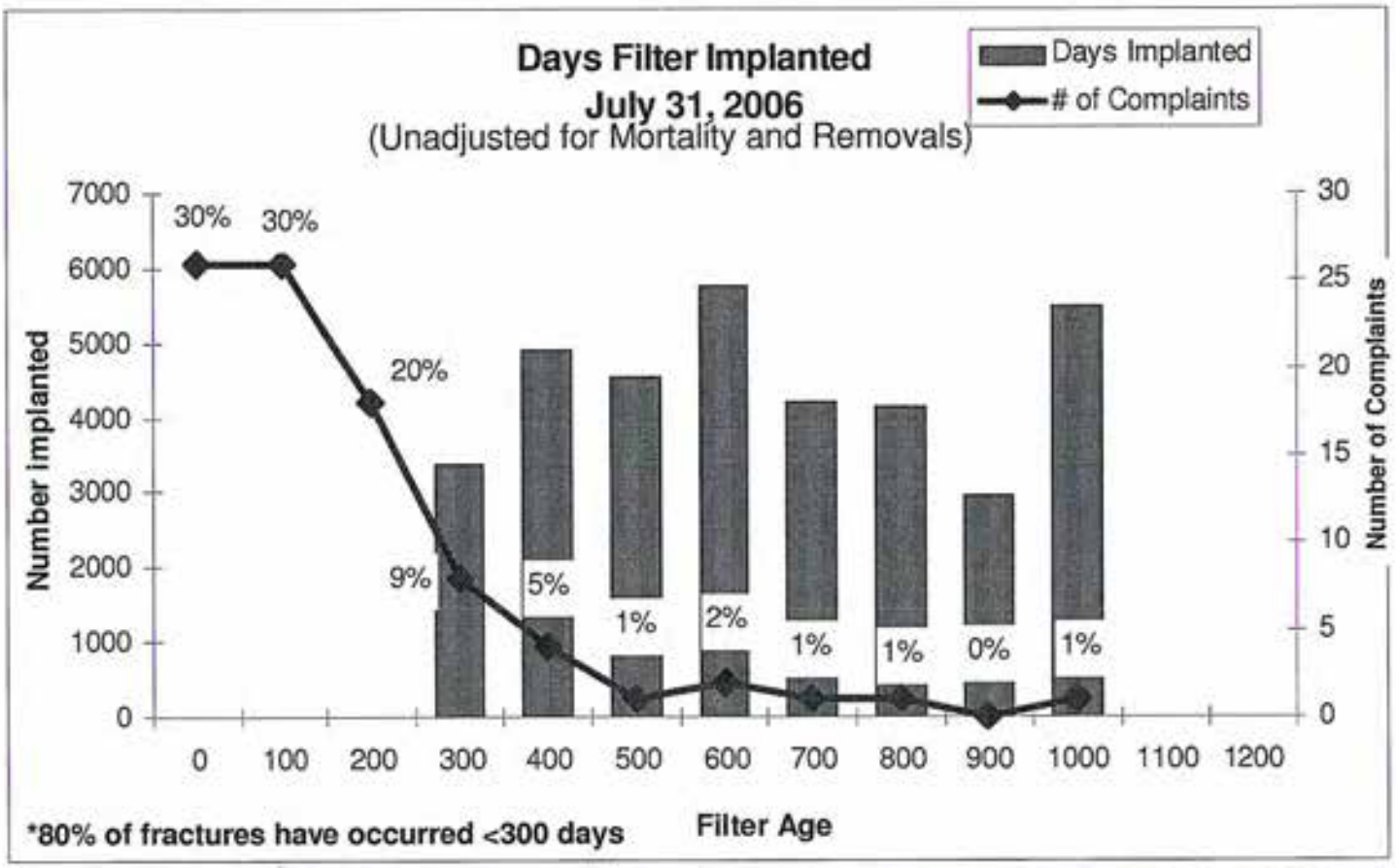
Recovery Complaint Trend



99% of implants at 7/31/06 are >300 days

Summary of Scenarios

Scenario 1: Current Experience

- Based on
  - Current complaint rate 300+ Days
  - 1 Year Mortality Rates[1]

Scenario 2: Estimated Future Rate

- Based on
  - Estimated rates 300+ Days
  - 1 Year Mortality Rates[1]

[1] Greenfield, L.J. and M.C. Proctor. Twenty-year clinical experience with the Greenfield Filter. Cardiovascular Surgery. Vol. 3, No. 2, pp.199-205, 1995.

Scenario 1: RNF Future Complaints based on Current Complaint Experience

Units Shipped	34,315
Removals (15%)[1]	(5,148)
Mortality Rate (29%)[2]	(8,459)
Est. Potential Remaining Filters	20,708
Est. Future Asymptomatic Complaints (0.04%)[3]	8
Est. Future Symptomatic Complaints (0.01%)[3]	2

[1] Kaufmann, Kinney. Cone Sales and Grande et al.

[2] Greenfield, L.J. and M.C. Proctor. Twenty-year clinical experience with the Greenfield Filter. Cardiovascular Surgery, Vol. 3, No. 2, pp.199-205, 1995.

[3] Rates based upon filters implanted 300+ days.

Scenario 2: RNF Future Complaints based on Estimated Future Rate

Units Shipped	34,315
Removals (15%)[1]	(5,148)
Current Complaints (n = 116)	(116)
Mortality Rate (29%)[2]	(8,425)
Est. Potential Remaining Filters	20,626
Total Fracture Rate (1.56)[3]	(322)
Total Asymptomatic / Symptomatic Rate (84% / 16%)	271 / 51
Est. Future Asymptomatic Complaints (22%)[4]	60
Est. Future Symptomatic Complaints (21%)[5]	11

[1] Kaufmann, Kinney. Cone Sales and Grande et al.

[2] Greenfield, L.J. and M.C. Proctor. Twenty-year clinical experience with the Greenfield Filter. Cardiovascular Surgery, Vol. 3. No. 2. pp.199-205, 1995.

[3] Rate based on number of asymptomatic found during planned retrieval and number of symptomatic.

[4] Rates based on estimated retrieval and incidental rates 300+ days.

[5] Symptomatic rate based on percentage of symptomatic complaints 300+ days.

Summary of Scenarios

Scenario 1: Current Experience

- Asymptomatic = 8
- Symptomatic = 2

Scenario 2: Estimated Future Rate

- Asymptomatic = 60
- Symptomatic = 11

Impact of leaving fragment behind

Physician Recommendation

- Leave fragment if stable
- Evaluate risk / benefit if in heart

Our Data

- 189 fragments, 0.06% with problems reported (symptomatic rate)
- 55 complaints had serious complications (Type A complaints)

Literature Review

- Results are inconclusive for the analysis

Impact of Inverted Filter Arm

To date, we have received 9 reports of inverted filter arms

- 6 Filters were removed
  - 7 arms detached during removal
  - 2 arms detached and remain in patient
- 3 Filters remain
  - 2 arms are still attached
  - 1 arm detached during attempt to remove filter

Physician Recommendation

- Do not remove filter because of a inverted arm

Conclusions

- Current Rates are well below SIR Fracture Guidelines of 2-10%
- Occurrence Level "Occasional" per R002 has not changed since 1 year ago
- Estimated number of future asymptomatic RNF fractures is 8 - 60
- Estimated number of future symptomatic RNF fractures is 2 - 11
- Since filters have been implanted approx. 300 days, the estimated fracture model may change
- Physicians recommend leaving asymptomatic fragments and inverted filter arms alone
- For symptomatic fragments, physicians recommend evaluating the risk / benefit of removal

Potential Next Steps

- **Customer Letter**

  Content: Notify fracture rate, standard of care applies, risk / benefit – compared to competitors

  Scenario A: Letter to Physician with no action recommendations

  Scenario B: Letter to Physician with recommend monitoring

  Scenario C: Broad Communication to Physicians and Patients

  Pro

  - Communicating with customer current rates
  - Communicating with patient with current information

  Con

  - Does not provide additional information that physician does not already know
  - Notifying patients that may never have complications
  - Is there anything to tell them besides disclosure of the rates?
  - Current fracture rates are below disclosed SIR rates, may confuse physicians and patients

Potential Next Steps

- Recall Existing Inventory

  Pro
  - Update inventory with better performing filter

  Con
  - RNF still performs

- Explant

  Pro
  - Remove risk of future fracture

  Con
  - Risk of patient undergoing procedure
  - Filter may fracture during removal process

- No Field Action

  Pro

  Con
  - Future fractures

Action Items - Completed (Slide 1 of 2)

- Estimate existing field inventory worldwide
  - 298 units as of 8/31/06
    - U.S. Western Region (submitted by Bob DeLeon) - 30 units
    - U.S. Central Region (submitted by Jack Sullivan) - 125 units
    - U.S. Eastern Region (submitted by Bob Cortelezzi) - 100 units
    - Europe (submitted on behalf of Kurt Delanghe by Frank Borremans) - 13 units
    - Canada (submitted by Monica Coutanche) - 30 units
    - Australia (submitted by Mandy Crispin) - 0 units
- Estimate percentage of fractured implants
- Update Spreadsheet (Patient Comparison Matrix)
- Gather intelligence on impact of leaving fragment behind
- Canada call with Chris, Pete, Paul, Gin and Bard Canada Regulatory.
- Update Risk/Benefit Analysis – **Review Draft**
- Document action items in R002 format– **Review Draft**

Action Items – Ongoing (Slide 2 of 2)

- BPV will obtain CT surgeon input
  - Dr. Ciavarella, Janet and Gin met on Aug 29th to plan strategy.
  - Meeting scheduled for October 12, 2006
- Evaluate complaint typing based on June panel input
- Continue Monitoring
  - Monthly Review with BPV Management Board
  - If we exceed our symptomatic number of complaints, then BPV PAT will re-convene
- Continue with update meetings. Update with Corporate on October 3, 2006

Backup Slides / Physician Review Slides

Data as of 8/31/06

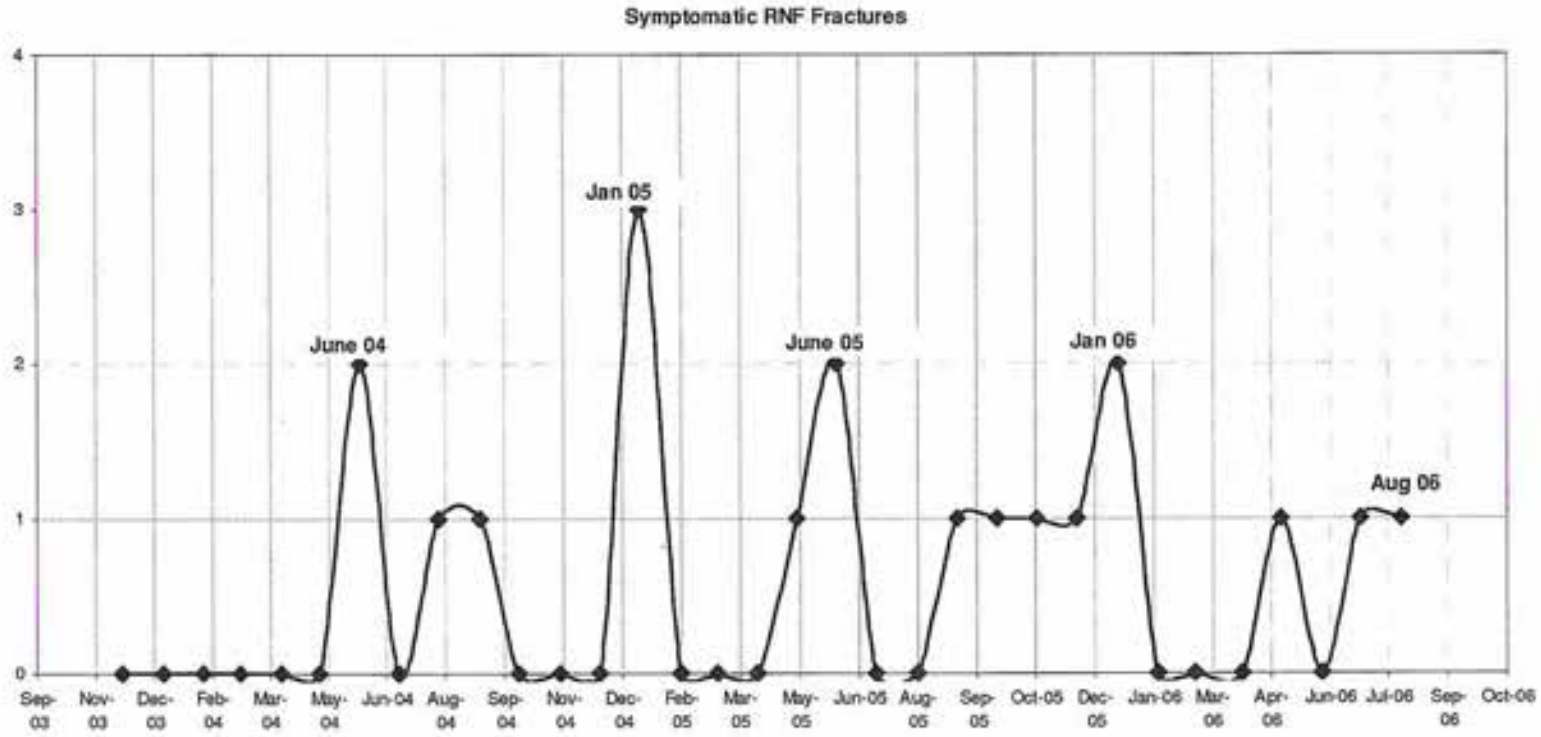
Recovery Complaint Trend (Slide 2 of 2)

- Data for previous slide

Timeline	Sales	# of Complaints	A	S	U
Prior to Dec-03	Approx. 5,482				
Dec-03	841	1	1	0	0
Jan-04	833	0	0	0	0
Feb-04	1276	1	1	0	0
Mar-04	1363	2	2	0	0
Apr-04	1333	4	4	0	0
May-04	1440	2	2	0	0
Jun-04	1427	6	4	2	0
Jul-04	1480	2	2	0	0
Aug-04	1290	3	2	1	0
Sep-04	1573	4	2	1	1
Oct-04	925	5	5	0	0
Nov-04	1621	1	1	0	0
Dec-04	1632	5	1	0	4
Jan-05	1958	5	1	3	1
Feb-05	1559	5	0	0	5
Mar-05	1604	3	2	0	1
Apr-05	1409	2	2	0	0
May-05	1598	3	0	1	2
Jun-05	1880	8	2	2	4
Jul-05	1224	6	3	0	3
Aug-05	1351	5	2	0	3
Sep-05	789	5	2	1	2
Oct-05	0	2	0	1	1
Nov-05	0	6	1	1	4
Dec-05	-973	7	1	1	5
Jan-06	0	4	1	2	1
Feb-06	0	4	1	0	3
Mar-06	0	1	0	0	1
Apr-06	0	2	0	0	2
May-06	0	2	0	1	1
Jun-06	0	4	2	0	2
Jul-06	0	5	4	1	0
Aug-06	0	1	0	1	0
Total	**34315**	**116**	**51**	**19**	**46**

*Data based on Date Opened

Symptomatic RNF Fractures



The symptomatic data above shows a seasonal effect in June and January. REASON: People "tend to put off imaging studies and elective procedure for when they have time off." (summer and holiday) – T. Kinney.

Recovery Fracture Analysis

- How Discovered

  78 During Removal

  11 Unrelated Scan

  12 Chest Pain (includes bleeding in the heart)

  2 Abdominal Pain (includes diarrhea)

  1 Pericardial effusion

  1 General Patient Pain

  1 Signs of PE

  1 Syncope episode

  1 Autopsy

  8 Unknown

Recovery Fracture Analysis

Total Number Filter Detachments:

Arm	Leg	Hook	Limb
127	15	33	12

Number Filters & Fragments Remaining:

36 Filters
100 Arms
12 Legs
33 Hooks
8 Limbs

Total: **189** Filters / Fragments Remaining in 100 Patients

Recovery Fracture Analysis

Filter Number of Complaints Correlation

Tilt	Saluting Arm	Perforate / Penetrate	Cephalad Migration	Caudal Migration
17	7	20	8	4

Fracture and Tilt

9 Filters Removed
- 2 arms removed
- 11 arms remain
- 5 hooks remain

8 Filters Remain
- 11 arms remain
- 1 leg remain
- 2 limbs remain

Fracture and Saluting Arm

6 Filters Removed
- 7 arms detached during removal
- 2 arms detached and remain in patient
- 1 hook remain

3 Filters Remain
- 3 arms remain in patient
  - 2 arms are attached
  - 1 detached during attempt to remove filter

Literature Review

Author	Year	N	Device(s)	Fracture Rate
Kalva	2006	40	Recovery	7.5%
Kalva	2006	270	TrapEase	3%
Hoppe	2006	41	Tulip	0%
Oliva	2005	27	OptEase	0%
Grande	2005	106	Recovery	0%
Rosenthal	2004	94	OptEase	0%
Kinney	2003	n/a	Combined	1%
Grassi	2003	n/a	Combined	2-10%
Rousseau	2001	65	TrapEase	0%
Streiff	2000	107	BN	2.8%
		71	SNF	14.1%
		117	VT-LGM	1.7%

Literature Review

Author	Year	N	Device(s)	Fracture Rate
Athanasoulis	2000	1731	MU, 24F SGF, BN, SNF, TGF, 12F SGF, VT-LGM, Protect-Cath, Tempo Filter	0.2%
Harries	1998	11	Antheor	27.3%
Greenfield	1998	65	24F SGF	4.6%
Greenfield	1995	642	24F SGF	2%
Ferris	1993	26	BN Type 1	3.8%
		32	BN Type 2	3.1%
		27	Amplatz	0%
		17	SNF	11.8%
		72	VT-LGM	1.4%
		6	TGF - Original	0%
		50	TGF - Modified Hooks	0%
		230	Combined	2.2%
Greenfield	1992	60	24F SGF	3.3%
Taylor	1991	81	VT-LGM	1.2% [25]

Physician Input (Slide 1 of 5)

- BPV Management met with Dr. Tom Kinney (UCSD) and Dr. John Kaufmann (Dotter Institute / OHSU) separately on August 16th 2006

Summary of Discussion

- Filter retrieval rates
  - Approximately between 15-20%
  - Grande's retrieval rate is indicative of actual clinical practice at 14% (Grande et al, JVIR, 2005).
- Complaints that do not indicate whether a patient is asymptomatic or symptomatic, can be assumed to be asymptomatic.
- Failure mechanism is levered limb that is stressed to point of fracture
- Severity Typing
  - Type "A"
    - Symptomatic migration of a limb outside the vasculature
    - Any fragment in the heart.
  - Type "B"
    - Asymptomatic migration of a limb outside vasculature

Physician Feedback Severity Typing with respect to vasculature and symptomatic:

(Slide 2 of 5)

Type	Severity Description
A	• Embolization of the fragment to heart or lung • Symptomatic migration of the fragment anywhere outside the vasculature • Any additional surgery (except filter removal) or medical treatment related to the presence of the fragment
B	• Fragments all retrieved during filter removal procedure • Fragments left in the IVC with no residual adverse effect • Asymptomatic migration of the fragment anywhere outside the vasculature • Any other situation where no treatment or surgery was undertaken due to the presence of the fragment

Physician Input (Slide 3 of 5)

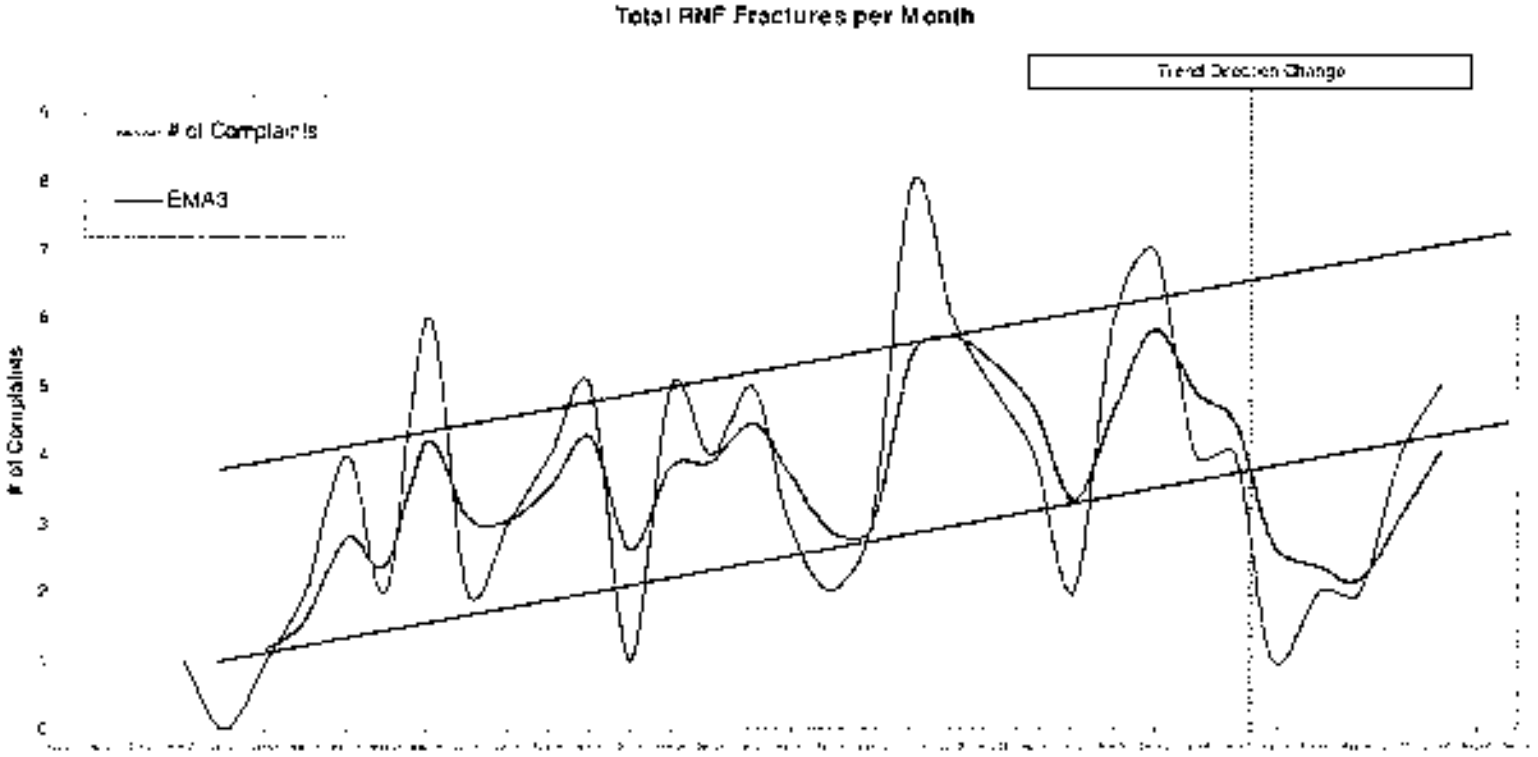
- Clinical implications of Chest Pain
  - Attributing chest pain is conservative.
  - Need to evaluate medical records to link the chest pain to fragment.

- Clinical implications of leaving a compromised filter in the body
  - Both physicians defined a "compromised" filter as one that no long provides adequate protection from recurrent PE.
  - A CT would indicate if the filter is providing adequate coverage.
  - If continued PE protection is needed and the physician has determined the filter is "compromised", he/she should replace the filter or place another filter above the compromised filter if retrieval is not possible.

- Clinical implications of leaving metallic parts not as concerning
  - History of leaving clips behind and metallic parts in the lungs
  - When fixed, little concern
  - If patient asymptomatic, aggressive treatment is not indicated
  - Possible course of action
    - Do nothing
    - Monitor KUB 1X/Yr, if no movement, no additional follow-up
    - If in heart, perform risk-benefit analysis
    - If in lung, most likely leave behind

Physician Input (Slide 4 of 5)

- Using RNF Fractures per month with an exponential moving average is a better method of analyzing the data rather than a month to month analysis.



Physician Input (Slide 5 of 5)

- Trend data
  - Graphs shows that fractures occur early
  - June/July spike not of concern as the raw numbers are small
  - Peaks in Summer and Year end could be due to activity level, year-end appointments, and maximize insurance benefits for the year
- Other data analysis
  - Not seeing recurrent PE
  - Changes in patient population with advent of retrievable filters
    - Younger/active (e.g. prophylactic) w/ shorter in-dwell time
    - "Classic" filter patients for recurrent PE

Conclusions

- Continue monthly review of the complaint information
- Advise against physician notification
  - Data does not warrant a notification
  - "We have no data to suggest what's good therapy." T. Kinney

& *July* Fracture Complaints – Type I, II, & III

Complaint Number	Summary of Event Description	Type	Time to Discovery
	• Arm detached has not been removed • Filter remains implanted • No patient injury reported.	I	854 days
	• Arm detached • Unsuccessfully attempted to remove the filter • No report of patient injury noted.	II	605 days
92677	• The Doctor retrieved a G1 filter f[illegible] patient without any particular difficulty. Upo[illegible]on, they noticed that a hook was missing.	II	None reported
	• One upper arm f[illegible] was embedded in the renal vein. • The filter w[illegible]ed, but the fragment remains embed[illegible] renal vein. • N[illegible]ite filter and no patient injury noted.	III	302 days
92707	A filter limb detached and migrated to the right renal vein.	III	1004 days

Typing will be updated based on discussion with CT

June & *July* Fracture Complaints – Type IV

Complaint Number	Summary of Event Description	Type	Time to Discovery
89513	• 3 filter arms were discovered to be detached • "sub-massive" PE • Tilted 90 degrees • Apex was embedded in the cava wall	IV	371 days
91690	• It was reported that one arm was in the pulmon[illegible] and one in the right ventricle.	IV	394 days
92793	• Removal of the Recovery filter with r[illegible]one. 9 days after the Recovery filter was placed. [illegible]oved with two of the arms missing. 15 yr old pa[illegible] viral myocarditis. Developed lower limb deep vein th[illegible]. Filter placed approximately June 23/06 by IR [illegible] days later presented with diarrhea and abdome[illegible]s done, filter was seen on x-ray and 2 arms missing [illegible] • PA [illegible] noted in **right ventricle which migrated to lung**. [illegible]al of filter took place nine days on July 2/06. (Detailed x-[illegible]s on CD).	IV	17 days
93374	• It was reported that portions of a Bard Recovery filter were discovered to have migrated to a patient's heart and lung 16 months after implant. • A fragment was removed from the **patient's right ventricle**, but one fragment remains in the patient's left **lower lobe of the lung.**	IV	475 days

Typing will be updated based on discussion with CT

Complaint 92793 - *updated*

- Original report received, data was incorrect
- 17 year old female
- June 1st, Presented at hospital with Cardiac symptoms
  - Right femoral catheterization, clots in femoral vein
  - Punctured septum to decrease cardiac pressure
  - Placed RNF filter
- June 2nd, abdominal X-Ray
  - 2 filter arms horizontal
  - filter tilted
- June 10th, abdominal X-Ray
  - No filter status change
- June 17th, abdominal X-Ray
  - 2 filter arms fractured: 1 located above filter, 1 unknown location
  - filter not tilted
- June 23rd, Chest Film
  - Fractured arms are now in chest: 1 in pulmonary artery, 1 in right ventricle
  - filter not tilted
- June 24th, Filter removed
- August, SNF placed at another hospital

- Patient is currently asymptomatic relative to the fractures
- Cardiologists want to treat her original symptoms, then determine action for the filter arm in the heart
- BPV has documented film history

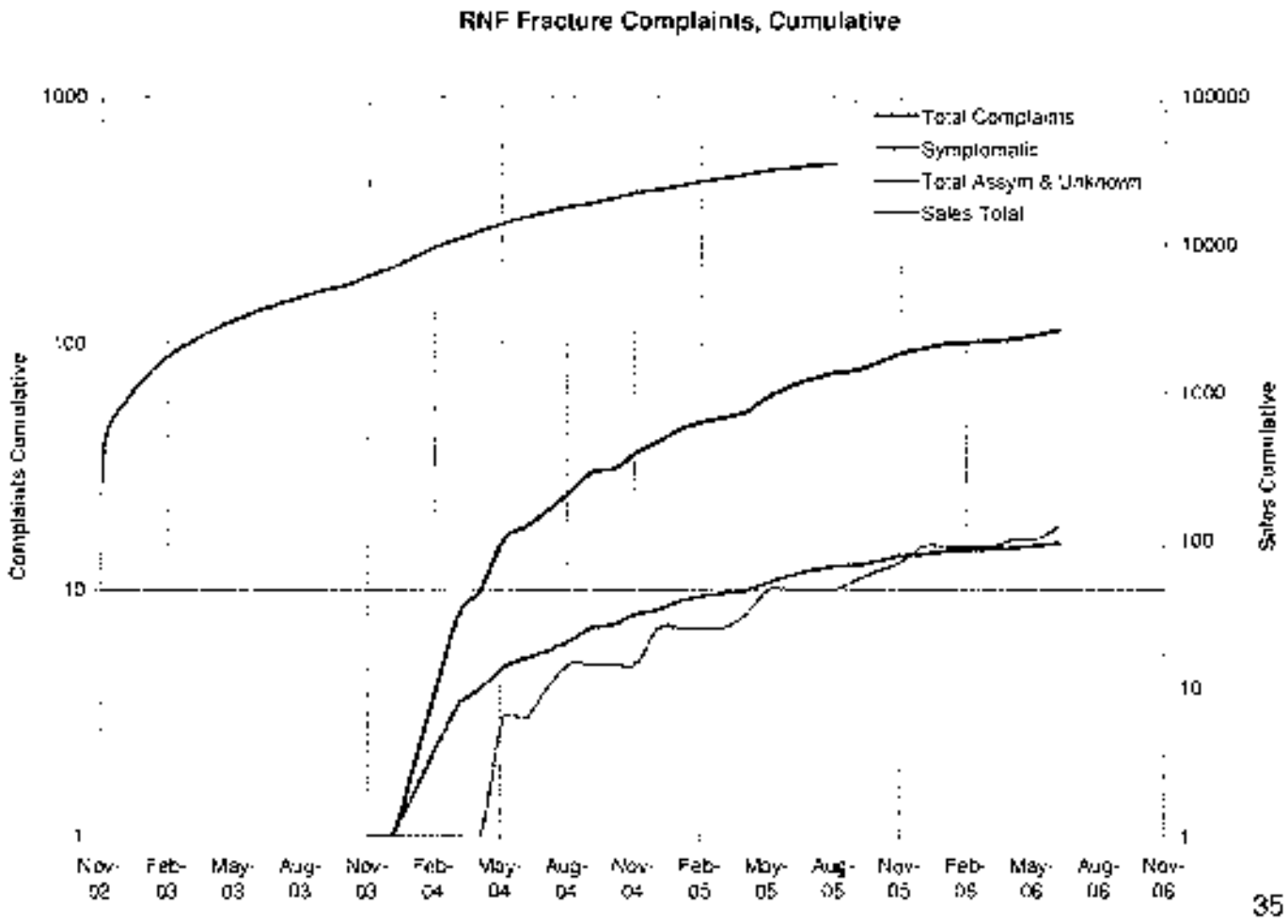
Fracture Severity Description

by: Team / Dr. Ciavarella / Dr. Kaufman

Type	Severity Description	Filter Status
I	Fractured filter segment, asymptomatic - no action required/taken, no patient injury	Filter still providing primary function of protection from PE
II	Fractured filter segment, reintervention to remove filter and/or component segments, mino[illegible] patient injury	[illegible]viding primary function of protection [illegible]om PE
III	Fractured [illegible] reintervention to remove fil[illegible]gments, and/or to repair da[illegible]e to patient's anatomy, patient injury	Filter no longer providing primary function of protection from PE (i.e. excessive tilt, arm/leg in side branch, or embolization to lung), perforation, or injury
IV	Fractured filter segment, reduction in filter efficiency causing pulmonary embolism, filter or portion of filter embolization to heart, life threatening, or death	Filter no longer providing primary function of protection from PE (i.e. excessive tilt, arm/leg in side branch, or embolization to heart), perforation, life threatening injury, or death

Typing will be updated based on discussion with CT

RNF Fracture Complaints, Cumulative



Hypothesis

- Since filter is removable, patients are monitored more closely for potential removals. Therefore, higher asymptomatic rates are expected compared to permanent filter.

- For filters removed, majority retrieved 3 – 6 months after implant.

- Based on RNF discontinued in Sept 2005, assumed complaints would diminish after June 2006.

Fracture Severity Description: Type A&B

Type	Severity Description
A	• Embolization of the fragment to heart or lung • Migration of the fragment anywhere outside the vasculature • Any additional surgery (except filter removal) or medical treatment related to the presence of the fragment
B	• Fragments all retrieved during filter removal procedure • Fragments left in the IVC with no residual adverse effect • Any other situation where no treatment or surgery was undertaken due to the presence of the fragment

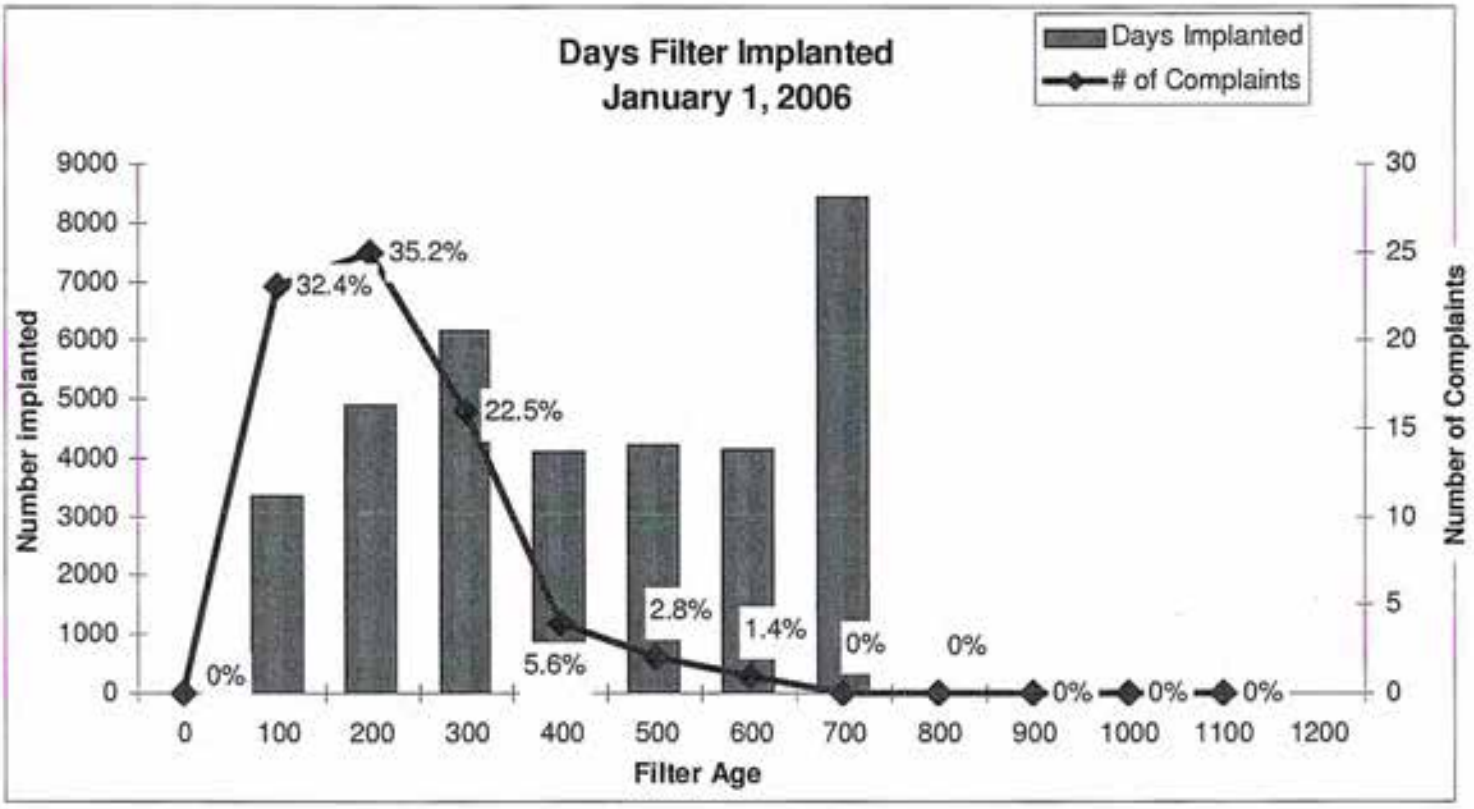
Literature Review – Fragments Remaining (Slide 1 of 2)

Article	# of Patients	Location of Fragment	Fragment Type	Clinical Outcome	Operation
Dato 1999	12	Right atrium	Grenade fragment	Arrhythmia	Y
		Right ventricle	Bullet 4mm Ø	Asymptomatic	N
		Left ventricle	Bullet 6.35 caliber	Asymptomatic	N
		Right ventricle	Bullets	Hemopericardium	Y
		Right ventricle	Bullets	Asymptomatic	N
		Left ventricle	Needle	Fever	Y
		Left atrium	Needle	Fever	Y
		Left atrium	Valvothomy ring	Asymptomatic	Y
		Pulmonary artery	Venous catheter	Ansia	Y
		Right ventricle	Venous catheter	Asymptomatic	Y
		Right ventricle	Rotating saw fragment	Cardiac tamponade	Y
		Pulmonary artery	Needle	Asymptomatic	N
Dato 2003	14	Right ventricle	Bullet	Asymptomatic	N
		Right ventricle	Bullet	Cardiac tamponade	Y
		Right ventricle	Bullet 4mm	Asymptomatic	N
		Left ventricle	Bullet 6.35 mm	Asymptomatic	N
		Left ventricle	Needle	Fever	Y
		Left atrium	Needle	Fever	Y
		Pulmonary artery	Needle	Asymptomatic	N
		Right ventricle	Venous catheter	Asymptomatic	Y
		Right atrium	Swan-Ganz catheter	Asymptomatic	Y
		Pulmonary artery	Venous catheter	Anxiety	Y
		Pulmonary artery	Venous catheter	Thoracic pain	Y
		Right atrium	Grenade fragment	Arrhythmia	Y
		Right ventricle	Circular saw	Tamponade	Y
		Left atrium	Valvulotomy ring	Asymptomatic	Y

Literature Review – Fragments Remaining (Slide 2 of 2)

Article	# of Patients	Location of Fragment	Fragment Type	Clinical Outcome	Operation
Farrell 1998	3	Pulmonary artery, right ventricle	Guide wire		Y
		Left atrium	Venous catheter	-	Y
		Pulmonary artery	Biopsy catheter	-	Y
Kim 2001	12	Right lower lobe	Metallic pin	Chest discomfort	Y
		Bronchus intermedius	Metallic cross	-	-
		Esophagus	Bone fragment	Chest and abdominal pain	Y
		Right hemithorax	Glass		Y
		Bronchus of lower left lobe	Hollow wood	Obstructive pneumonitis	Y
		Bronchus of upper right lobe	Gloriace fragment	Right chest discomfort	-
		Right ventricle	Sewing needle	Asymptomatic	Y
		Left upper lung	Surgical sponge	-	Y
		Left hemidiaphragm	Surgical gauze	-	
		Right hemithorax	Paraffin	Calcified nodule	-
		Right lower lung	Solid fragment, multiple needles	Pulmonary nodule	-
		Carina	Esophageal stretch device	Sudden dysphonia	Y
Poletan 2002	1	Right ventricle	TrapEase filter	Severe cardiac shock, cerebral and right arm paradoxical embolism	Y
Schreiber 2001	1	Right ventricle, right middle pulmonary artery, bronchus	Sternal wire	Massive hemoptysis	Y
Van Der Akker-Berman 2002	1	Right atrium and ventricle	Intravenous catheter	Asymptomatic	Y

Recovery Complaint Trend (Slide 1 of 2)



SIR, RNF, G2, and SNF Rate Comparison

- Complication/Trackable Event Rates from **SIR Guidelines** (all filters)* is **2-10%**
- **RNF** had 116 Fractures (as of 8/31/06)
  - Unit Sales 34,315
  - Fracture Complaint Rate = **0.34%**
- **G2** had 4 Fractures (as of 8/31/06)
  - Unit Sales 21,289 (through August)
  - Fracture Complaint Rate = **0.02%**
- **SNF** had 3 Fractures (3/04-12/05)
  - Unit Sales 22,618 (3/04-12/05)
  - Fracture Complaint Rate = **0.01%**

* Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. J Vasc Interv Radiol 2003; 14:S271-S275.

Recovery Fracture Analysis

- Asymptomatic vs. Symptomatic:
  - 52 patients are asymptomatic, 73%
  - 19 patients are symptomatic, 27%
  - 45 patients are unknown

	Asymptomatic		Symptomatic		Unknown	Total
Female	32	76%	10	24%	21	63
Male	7	64%	4	36%	9	20
Unknown	13	72%	5	28%	15	33
Total	52	73%	19	27%	45	115

Literature Review – Fragments Remaining (Slide 1 of 3)

Clinical Outcome of Leaving Fragment Behind

Of the 44 Patients:

- 22 Symptomatic, 50%
  - 4 Fevers
  - 3 Cardiac Tamponade
  - 1 Ansia
  - 1 Anxiety
  - 2 Arrhythmia
  - 1 Calcified Nodule
  - 1 Chest and Abdominal Pain
  - 1 Chest Discomfort
  - 1 Hemopericardium
  - 1 Massive hemoptysis
  - 1 Obstructive pneumonitis
  - 1 Pulmonary nodule
  - 1 Right Chest Discomfort
  - 1 Severe cardiac shock, cerebral and right arm paradoxical embolism
  - 1 Sudden dysphonia
  - 1 Thoracic Pain
- 15 Asymptomatic, 34%
- 7 Unknown, 16%

Literature Review – Fragments Remaining (Slide 2 of 3)

Were the Fragments Removed

- 31 Operations to Remove Fragment
  - 7 were asymptomatic (all in heart, 2 needles, 5 bullets)
- 8 Not Removed
  - All were asymptomatic
- 5 Unknown

Fragments Types:

- 9 Bullets
- 7 Needles
- 6 Venous Catheter
- 3 Grenade Fragments
- 2 Circular saw / Rotating saw fragment
- 2 Valvothomy ring
- 1 TrapEase filter
- 1 Bullet and multiple needles
- 1 Bone fragment
- 1 Broviac catheter
- 1 Esophageal speech device
- 1 Guide wire
- 1 Hollow wood
- 1 Intravenous catheter
- 1 Metallic cross
- 1 Metallic Pin
- 1 Paraffin
- 1 Sternal wire
- 1 Surgical gauze
- 1 Surgical sponge
- 1 Swan-Ganz catheter
- 1 Glass

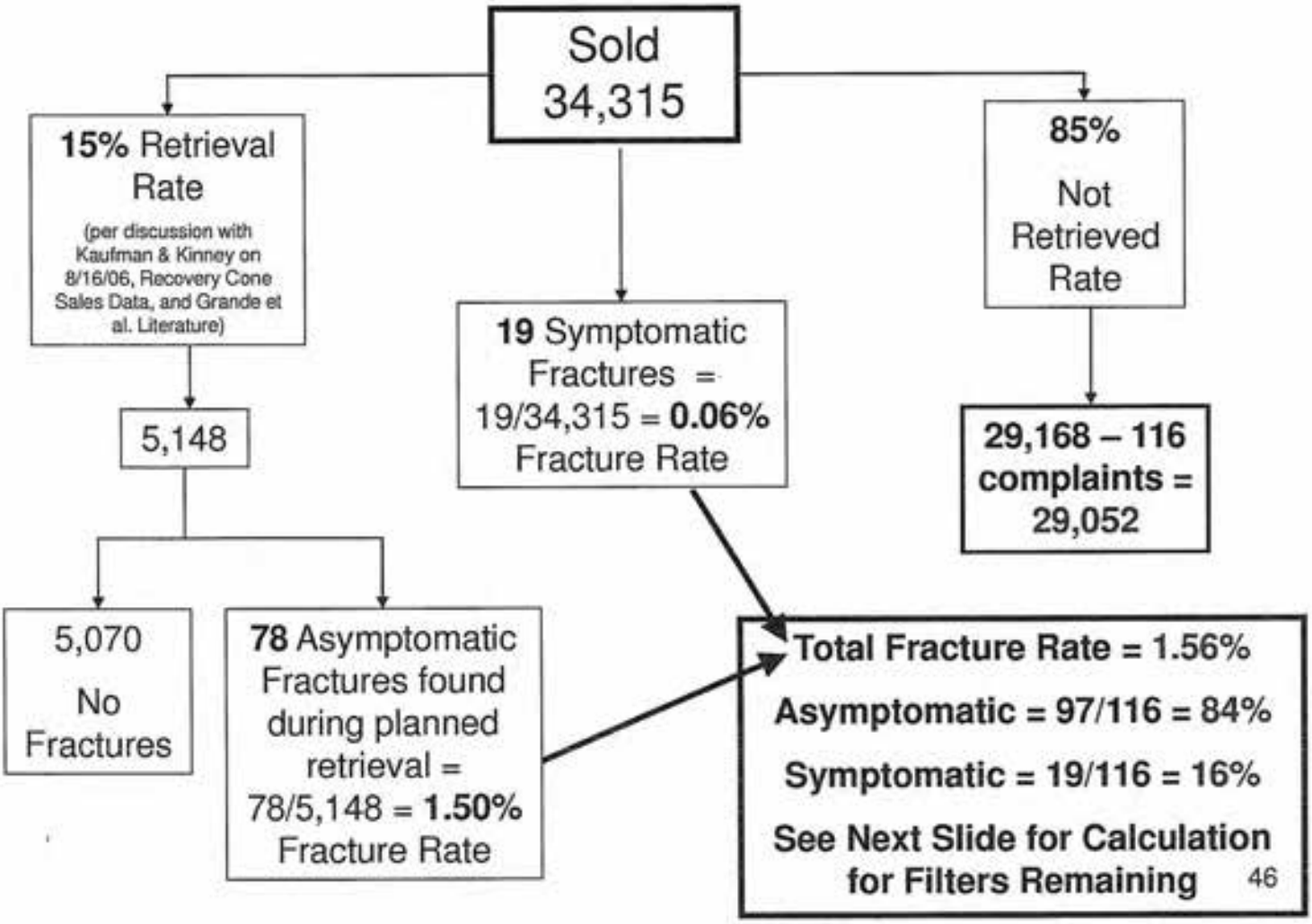
Literature Review – Fragments Remaining (Slide 3 of 3)

Conclusions*

- Symptomatic foreign bodies should be removed irrespective of their location
- Asymptomatic foreign bodies diagnosed immediately after the injury with associated risk factors should be removed
- Asymptomatic foreign bodies without associated risk factors or diagnosed late after injury may be treated conservatively, particularly if they are completed embedded in the myocardium or in the pericardium.

* Actis Dato GM, et al. Posttraumatic and iatrogenic foreign bodies in the heart: report of fourteen cases and review of the literature. J. Thorac Cardiovasc Surg. 2003 Aug; 126(2): 408-14.

Estimated Filter Fracture Distribution



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Scenario 2 Filter Fracture Distribution (Slide 1 of 2)

Patient Types	Distribution	Implants Remaining* (Dist*29,052)	Mortality Rate at 1 yr (20 yr Greenfield Experience*)	Mortality Number**	Final Implants Remaining
Trauma	32%	9,297	29%	2696	6,601
Orthopedic	27%	7,844	29%	2275	5,569
Cancer	16%	4,648	29%	1348	3,300
Bariatric	18%	5,229	29%	1517	3,713
High Risk Procedures	7%	2,034	29%	590	1,444
Total	**100%**	**29,052**		**8,425**	**20,627**

*Greenfield, L.J. and M.C. Proctor. Twenty-year clinical experience with the Greenfield Filter. Cardiovascular Surgery, Vol. 3, No. 2, pp.199-205, 1995

**Numbers are rounded to the nearest whole number

Scenario 2 Filter Fracture Distribution (Slide 2 of 2) DRAFT

Patient Types	Final Implants Remaining	1.56% Total Fracture Rate	84% Asymptomatic	16% Symptomatic
Trauma	6,601	103	87	16
Orthopedic	5,569	87	73	14
Cancer	3,300	51	43	8
Bariatric	3,713	58	49	9
High Risk Procedures	1,444	23	19	4
Total	**20,627**	**322**	**271**	**51**

After 300d, Asymptomatic
- 2% are Retrieved
- 20% are Incidental
- 22% Total = 271 * 22% =

60 Asymptomatic Complaints Expected

After 300d, Symptomatic
- 4/19 Complaints = 21%
- 51 * 21% =

11 Symptomatic Complaints Expected

Hypotheses

- Original
  - Since filter is removable, patient are monitored more closely for potential removals. Therefore, higher asymptomatic rates are expected.
  - Assuming last filter implant at the end of 2005 and patient is monitored for 6 months post-implant.
  - Monitor for maximum of 2 asymptomatic complaints per month through June 2006.
- Amended
  - Based on physician input, patients could be monitored longer than 6 months.

Further Evaluation

- Clinical implications of leaving a filter in the body
- Clinical implications of leaving a detached limb in the body
- Inventory remaining in the field
- Instructions on how to manage a compromised filter

Discussion Points

- Clinical implication of a free floating limb in the body, likely scenario and worst case scenario:
  - IVC
  - Renal Vein
  - Retroperitoneum
  - Heart
  - Lung
- Clinical implications of leaving a detached limb in the body
- Clinical implications of leaving a compromised filter in the body
- Instructions on how to manage a compromised filter
- Of these installed based, how many future retrievals?
- Predict future events, risk, rates, etc.
- Should patients with RNF be monitored long term?

Action Items (Slide 1 of 2)

- Update Spreadsheet (Patient Comparison Matrix)
  - Update through current information
  - Add whether a fragment was remained in patient and the consequence
  - Expected Completion Date: Sept 1 (Update through current complaints), Sept 29 (Finalize data)
- Evaluate complaint typing based on June panel input
  - Expected Completion Date: Aug 31 (Definition Complete), Sept 29 (Categorize Complaints to Typing)
- Gather intelligence on impact of leaving fragment behind
  - Bard data
  - Literature search, e.g. Endoscopic Data
  - Studies
  - Expected Completion Date: Sept 29
- Update Risk/Benefit Analysis
  - Expected Completion Date: TBD - would need updated Patient Comparison Matrix to complete

Action Items (Slide 2 of 2)

- Draft Notification
  - Fractures known complication
  - Our history is…
  - Within guidelines
  - If physician decides to evaluate patients ….
  - If you see these scenarios, you might want to consider… (unknown at this point)
  - Pending Completion of Action Items
- Continue Monitoring
  - Ongoing
- Estimate existing field inventory worldwide
  - Expected Completion Date: Aug 31
- Estimate percentage of fractured implants
  - Based on all available data, what percent of implants would expect to have fractures?
  - Expected Completion Date: Aug 31
- Document action items in R002 format
  - Expected Completion Date: Aug 22 (Draft addendum), Document will be finalized at completion of action items

EXHIBIT G

Recovery® Filter System

Special 510(k) Submission
K022236

November 27, 2002

Ref :
Dept :

Date: 10JUL02 SHIPPING $7.73
Wgt: 1 LBS SPECIAL $0.00
HANDLING $0.00
TOTAL $7.73

SERVICE: PRIORITY OVERNIGHT
TRACK: 4628 6899 2713

IMPRA
A Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740
TEL: 800-321-4254
480-894-9515
FAX: 480-966-7062

IMPRA

July 10, 2002

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Recovery™ Filter System
Special Premarket Notification

Dear Sir or Madam,

Impra Division of C. R. Bard, Inc. hereby submits this **Special 510(k): Device Modification** to request modifications to our Simon Nitinol Filter/Straightline™ System.

The modifications to the intravascular filter are:

- The wire diameter has been reduced from 0.014" to 0.013";
- The closed dome shape (petal-like dome) has been changed to an open design;
- One sleeve that holds the filter wires to the body of the filter has been eliminated; and
- The hooks that engage the vena cava wall have been tapered.

The modifications to the filter delivery system are:

- The nitinol pusher wire, previously coated with PTFE, is now made of polished nitinol without the PTFE coating;
- The pusher pad is smaller, to attach to the filter hooks instead of the filter apex;
- A spline has been added to the pusher pad to aid in centering the filter during deployment; and
- The wire distal to the spline has been tapered.

We believe that these modifications are eligible for review under the Special 510(k) process because they meet the requirements of "The New 510(k) Paradigm" final guidance issued on March 20, 1998.

BARD

Impra has not publicly disclosed or acknowledged the existence of this Special 510(k) to any individual outside its employ other than disclosure made under commercial agreements containing the appropriate safeguards for secrecy. As a result, Impra requests that FDA keep and maintain confidential both the existence and the contents of the Special 510(k) in accordance with 21 CFR 812.38(a). Impra also requests that FDA keep and maintain confidential the contents of this letter.

If you have any questions, please contact Kay Fuller by telephone at (480) 303-2539 or by fax at (480) 449-2546.

Regards,

Kay Fuller
Senior Regulatory Affairs Specialist

Carol Vierling
Director, Regulatory Affairs

Special 510(k)—

Recovery™ Filter System

TABLE OF CONTENTS

Special 510(k)—

Recovery™ Filter System

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CDRH SUBMISSION COVER SHEET

Date of Submission: July 8, 2002 **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ☐ Traditional ■ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B **Applicant or Sponsor**

Company/Institution Name: C. R. Bard, Inc.		Establishment registration number: 2020394	
Division Name (if applicable): IMPRA, Inc.		Phone number (include area code): (480) 303-2539	
Street Address: 1625 West 3rd Street		Fax number (include area code): (480) 449-2546	
City: Tempe	State/Province: AZ	Zip code: 85281	Country: USA
Contact Name: Kay Fuller			
Contact Title: Senior Regulatory Affairs Specialist		Contact e-mail address: kay.fuller@crbard.com	

Section C **Submission Correspondent (if different from above)**

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country
Contact Name:			

Section D1 **Reason for Submission – PMA,PDP, or HDE**

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing Agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location Change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Processing Change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other (specify below)_
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post Approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in Ownership
- ☐ Change in correspondent
- ☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

Change in:

- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:

- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:

- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 **Reason for Submission – 510(k)**

- ☐ New Device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ■ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Section E	Additional Information on 510(k) Submissions			
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ■ 510(k) summary attached ☐ 510(k) statement
1 2120F	2 2120J	3 2320A	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K944353	1 Simon Nitinol Filter/Straightline System	1 Bard—Glens Falls Operations
2 K901659	2 Titanium Greenfield Vena Cava Filter	2 Boston Scientific
3	3	3
4	4	4
5	5	5
6	6	6

Section F	Product Information – Applicable to All Applications
Common or usual name or classification name: Filter, intravascular, cardiovascular	

Trade or proprietary or model name	Model Number
1 Recovery™ Filter System	1 RF-048F
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ■ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G	Product Classification – Applicable to All Applicants	
Product code: DTK	C.F.R. Section 870.3375	Device Class: ☐ Class I ■ Class II ☐ Class III ☐ Unclassified
Classification Panel: Cardiovascular		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

■ Original ☐ Add ☐ Delete	FDA establishment registration number: 1313046	■ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution name: C. R. Bard, Inc.		Establishment registration number:	
Division name (if applicable): Glens Falls Operations		Phone number (include area code): (518) 793-9283	
Street address: 289 Bay Road		FAX number (include area code): (518) 792-3768	
City Queensbury	State/Province NY	Zip code: 12804	Country USA
Contact name: Pete Palermo			
Contact title: Corporate Director of Quality Control			

■ Original ☐ Add ☐ Delete	FDA Establishment registration number: 1018233	☐ Manufacturer ■ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution Name: C. R. Bard, Inc.		Establishment registration number:	
Division name (if applicable): Bard Regional Sterilization		Phone number (include area code): (770) 784-6760	
Street address: 8195 Industrial Blvd.		FAX number (include area code): (770) 784-6416	
City: Covington	State/Province: GA	Zip code: 30014	Country: USA
Contact name: Brian Drumheller			
Contact title: Quality Assurance Manager		Contact e-mail address:	

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:		Contact e-mail address:	

Device Name

The device trade name and common/classification name is:

Device Trade Name	Common/Classification Name
Recovery™ Filter System	Cardiovascular intravascular filter

Address and Registration Number

The address and registration number of the manufacturer and sterilization site for both the Bard predicate (Simon Nitinol Filter/Straight Line™ System) and the Recovery Filter is:

Manufacturer	Sterilization Site
(Bard) Glens Falls Operation 289 Bay Road Queensbury, NY 12804 FDA Registration #: 1313046	Bard Regional Sterilization 8195 Industrial Blvd. Covington, GA 30014 FDA Registration #: 1018233

Device Class

Intravascular filters have been classified as Class II, DTK. The document "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions", issued on November 26, 1999, has been designated as a special control for these devices.

Predicate Device Information

The device to be modified is the Simon Nitinol Filter/Straight Line™ System (SNF/SL System) which received marketing clearance on April 28, 1995 (K944353). Drawings of this predicate device and the modified device are provided in Attachment 1.

The Titanium Greenfield® Vena Cava Filter, manufactured by Boston Scientific, Corp., is a secondary predicate. This filter was cleared under K901659 on November 8, 1990. The notice of 510(k) clearance is provided in Attachment 2.

Labeling and Intended Use

The labels for the modified device are provided in Attachment 3. They indicate the new trade name and the femoral approach for filter placement (the Bard predicate device was available in either a subclavian, jugular, antecubital or femoral approach delivery system while the modified device can only be deployed via a femoral approach).

Truthfulness and Accuracy Statement

Pursuant to 21 CFR 807.87(j), I, Carol Vierling, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Director of Regulatory Affairs at C.R. Bard, Inc., and in reliance thereupon, the data and information submitted in this Premarket Notification are truthful and accurate and that no facts material for review of the substantial equivalence of this device have been knowingly omitted from this submission.

Carol Vierling
Director, Regulatory Affairs

7-10-02
Date

Intended Use

The modified intravascular filter is indicated for use in the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy in thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

This is the **same indication for use** as the SNF/SL System (Bard predicate device). Both filters are permanent implants. The Indications for Use statement for the modified device is provided in Attachment 4.

Filter Description and Comparison

The table below compares the predicate filter to the modified filter. **Changes are noted in bold type.**

	SNF/SL System (Bard predicate device)	Recovery Filter (modified device)	Modification
Material	Nitinol	Nitinol	No change in materials.
Wire Diameter	0.014"	**0.013"**	**The smaller diameter wire allows the open dome design and the legs to maintain the same collapsed profile as the predicate device.**
Design	A closed-dome (petal-like) configuration at the top with six nitinol wire legs that extend downward.	**An open dome configuration at the top with six nitinol wire arms.** There are six nitinol wire legs that extend downward.	**The dome shape has changed from a closed configuration to one that is open (six arms).**
	One sleeve directly above the dome holds the dome together and one sleeve directly below the dome hold the wire legs together.	**One sleeve directly above the dome holds the wire arms and legs together.**	**One sleeve directly above the dome holds the wire arms and legs together. This causes the legs to open more closely to the dome.** **The modified filter is more streamlined in design, allowing for a more simple manufacturing process.**
	The dome and legs provide a two-level filtering system.	The dome and legs provide a two-level filtering system.	The two-level filtering system is maintained.
	At the end of each leg is a small hook that attaches to the vena cava wall to help prevent filter migration.	At the end of each leg is a small hook that attaches to the vena cava wall to help prevent filter migration. **The wire of the hooks has been tapered slightly.**	The hooks continue to attach to the vena cava wall to help prevent filter migration. **The hooks have been tapered to lessen the potential for vena cava wall trauma.**

In summary, the wire diameter has been reduced, the dome is now open to form arms, there is only one sleeve and the wire hooks have been tapered slightly.

Filter Substantial Equivalence

The modified filter has the following similarities to those of the Bard predicate filter which received 510(k) concurrence:

- Same indication for use;
- Same material;
- Same basic two-level filtering design;
- Same operating principle;
- Both devices are single use only;
- Same packaging components; and
- Same sterilization method

On the following page is a diagram of the Bard predicate filter (Figure 1), the modified filter (Figure 2) and the secondary predicate, the Titanium Greenfield Filter Figure 3). These diagrams provide a side-by-side comparison of the three filters. A diagram of the caval coverage for each filter is also provided.

Drawings of Bard predicate and modified filters are provided in Attachment 1.

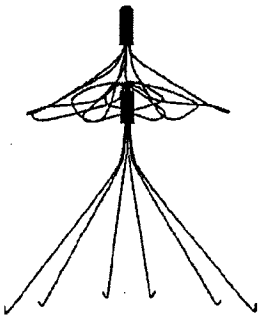


Figure 1

Bard SNF/SL Filer

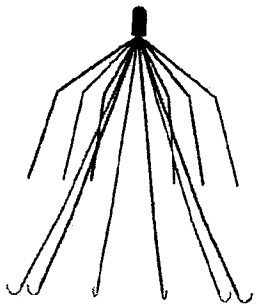


Figure 2

Recovery Filter

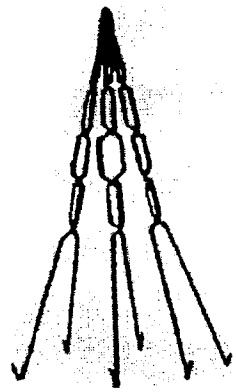
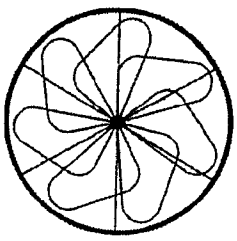
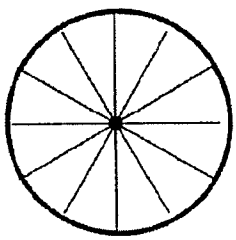
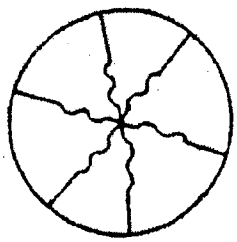


Figure 3

Titanium
Greenfield Filter







Caval Coverage for Each Filter

Delivery System Description and Comparison

The delivery system for both the Bard predicate and the modified device has the same components:

- Introducer Catheter (with two gold marker bands on the distal tip)
- Filter Storage Tube
- Side Port (to which the user connects a saline drip infusion set that is not part of the filter system)
- Adjustable Touhy-Borst Adapter
- Pusher Wire
- Pusher Wire Handle

Only the pusher wire component is being modified. The materials, design and operating mechanism for the other components remain the same.

The table below compares the pusher wire component for the Bard predicate system with that of the modified pusher wire. **Changes are noted in bold type.**

	SNF/SL System (Bard predicate device)	Recovery Filter (modified device)	Modification
Pusher Wire Material	PTFE coated nitinol wire	**Polished nitinol wire**	**Polished nitnol wire provides a smooth surface and eliminates the need for the PTFE coating.**
Pusher Wire Features	Pusher wire with either a stainless steel cup (for femoral route) or a stainless steel pad (for jugular/subclavian or antecubital route) and a handle.	Pusher wire with a stainless steel pad **with a stainless steel spline glued to the pusher pad. There is a "flexion point" (wire taper) distal to the spline.**	**The pad is smaller for the modified device because the pad is attached to the hooks of the filter instead of the filter apex. A spline has been glued to the pusher pad to hold the legs in place during delivery. The 'flexion point" helps to center the filter when deployed.**

In summary, the changes made to the pusher pad are 1) the PTFE coating has been eliminated, 2) the pusher pad is smaller, 3) a spline has been glued to the pusher pad and 4) the wire distal to the spline has been tapered (flexion point).

Delivery System Substantial Equivalence	The modified delivery system has the following similarities when compared to the Bard predicate delivery system that received 510(k) concurrence:

- Same basic design;
- Same operating principle; and
- Both delivery systems are single use only.

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a Failure Modes Effects Analysis (FMEA). In addition, the FDA guidance document, "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions" was used to determine the appropriate tests to be performed so that data could be gathered to support the safety and effectiveness of the modified device.

Based on the modifications to the filter and delivery system noted previously (and below), the following testing was performed:

Modifications to Filter
Reduced filter wire diameter
Open dome filter configuration
Single filter sleeve to hold arms and legs in place
Tapered hooks
Modifications to Delivery System
Elimination of PTFE coating on pusher wire
Smaller pusher pad
Addition of spline to pusher pad
Taper of wire distal to pusher pad spline (flexion point)

Tests Performed
Clot Trapping Efficiency
Migration Study
Weld Integrity
Hook Strength
Corrosion/Fatigue Testing
Radial Strength
Spline Glue Joint Tensile Test
Simulated Use Study

In addition, stability testing will be performed to support a 3-year shelf life.

Biocompatibility Testing	The material of the modified filter is the same as that of the Bard predicate (Nitinol) therefore, no biocompatibility testing of the filter was required. The modified delivery system has a glue joint not found in the Bard predicate delivery system which is the spline to pusher pad attachment. Loctite, a commonly used adhesive, bonds the spline to the pusher pad. Since Loctite is widely used in bond joints of medical devices, bicompatibility testing of the delivery system was not performed.
MRI Compatibility	An MRI compatibility claim for the Bard predicate device was supported in K944353, which received clearance on April 28, 1995. The minor changes made to the filter are such that MRI compatibility would not be affected therefore, additional testing was not performed and the modified filter labeling includes the same MRI compatibility claim.

Clot Trapping Efficiency

An *in vitro* model of the inferior vena cava (IVC), under strictly controlled and standardized hydrodynamic conditions comparable to those of the human body, was used to assess clot trapping ability of both the predicate (Titanium Greenfield Filter) and modified filter. This model is based on that originally described by Morris Simon, MD (Radiology, 1993, 189: 769-774).

Clot trapping efficiency was assessed by serially injecting five clots into the (pulsed) flow loop of the heated test model and then counting the number of clots trapped by the filter. Clots were prepared from fresh sheep blood and cut into 60mm lengths. Each clot was 5-6mm in diameter. The clots were delivered with a syringe one at a time in a series of five clots. After the fifth clot was delivered, the technician observed the filter for 1 minute and then removed the trapped clots. The series of tests was repeated 8 times in both the horizontal and vertical position for a total of 80 clots delivered to one Recovery Filter and 80 clots delivered to one Greenfield Filter.

Both the predicate and the modified device were tested in the same manner, using the same test equipment. Filters were positioned horizontally (to reflect normal use) and vertically (for "worst case" conditions).

The Titanium Greenfield Filter was the predicate device used for this test. This filter was chosen to determine if the Recovery Filter exhibited clot trapping ability better than that of the leading competitor. In order to meet acceptance criteria, the Recovery Filter must capture clots as well as or better than the Titanium Greenfield Filter.

Summary: In the horizontal position (normal use), the Greenfield Filter trapped 67% (27 of 40) and the Recovery Filter trapped 72% (29 of 40) of the clots delivered. In the vertical position (worst case), the Greenfield Filter trapped 65% (26 of 40) and the Recovery Filter trapped 90% (36 of 40) of the clots delivered. Based on this testing, the Recovery Filter met the acceptance criteria. The Recovery Filter has a higher efficiency for clot trapping than the Titanium Greenfield Filter in both the horizontal and vertical positions.

Migration Study

This testing was performed to determine the resistance of the filter to migration when fully occluded. Occlusion causes a significant increase in the pressure acting on the filter and represents a "worst case" condition for migration.

Clinicians were consulted to determine the maximum pressure that could be generated below an occluded IVC filter. The maximum pressure believed to be generated was 35mm Hg. A safety factor of 15 mm Hg was added so that in order to pass the test, the Recovery Filter and the SNF[1] (Bard predicate) must withstand 50mm Hg when fully occluded in 15mm and 28mm diameter IVC models.

The 15mm diameter model was chosen as representative of the smaller size vena cava that would be seen in medical practice. The 28mm diameter model is the largest size of vena cava in which the filter can be deployed, per the Instructions for Use.

A total of five Recovery Filters and three SNF Filters were placed in the two IVC models. Each filter was challenged three times in each tube size (15 and 28mm). The *in vitro* model was a clear plastic tube, lined with bovine intestine to simulate vena cava tissue. The test system included a heat reservoir, pressure sensor, cardiac pump and clot injection port. Clots were injected into the flow loop of the system to occlude the filter. This process continued until the filter migrated or until the maximum pressure that could be achieved in this test model was reached.

Summary: The maximum pressure that the flow model could generate below the filter was approximately 70mm Hg. In all of the 15mm diameter samples for both filters, pressures high enough to cause migration could not be achieved. Since the pressure at which the filter migrated could not be determined, the maximum pressure below the filter was recorded (peak pressure). The average peak pressure was 69.1mm Hg for the modified device and 67mm Hg for the SNF.

[1] The Bard predicate device noted in this 510(k) is the Simon Nitinol Filter/Straight Line System (SNF/SL). The words "Straight Line System" differentiate this product from the Simon Nitinol Filter (hoop system). The filter in both products is the same; only the configuration of the delivery systems (straight or hoop style) is different. In testing where only the filter is evaluated, the test samples are noted as SNF.

Migration Study (continued)	Migration of the Recovery Filter occurred in the 28mm diameter model between 57 and 75mm Hg (average pressure was 65.8mm Hg). Two of the SNF samples resisted pressures of 60 and 66mm Hg without migration. The third sample migrated at 68mm Hg. Both filters resisted migration when fully occluded in the 15mm and 28mm diameter vessels. All samples met the minimum acceptance criteria of 50mm Hg.

Weld Integrity

The Recovery Filter is manufactured in "bundles", with 12 wires (formed into 6 arms and 6 legs) and the sleeve (which holds the wires together). The weld joint (sleeve to wires) is a critical bond since it is the only point of wire attachment to the sleeve.

Visual inspection and tensile testing of the bond joint were performed on 30 bundles. One wire from the 9 outside wires located next to the sleeve and 1 wire from the 3 wires in the middle of the bundle were tested for each of the 30 bundles.

The diameter of the weld bead must be 0.072" +0.0120/ - 0.001". The bead height must be 0.170" +0.020/ - 0.010". The tensile strength of each point of attachment is a minimum of 5 lb.

Summary: All weld beads met the visual acceptance criteria. The average tensile strength of the weld was 14.66 lbf (min. 12.02, max. 18.94). Testing showed with 95% confidence that 99.9% of the wire population will withstand 5 lb. of tensile force.

Hook Strength

The strength of the Recovery Filter hooks was measured to determine their ability to withstand a minimum of 70 g force (equivalent to 50mm Hg pressure in a 28mm diameter vessel acting on a filter with 6 hooks). Seventy grams of force is equal to 79.5-106 g force acting on a single wire.

Testing was performed by pulling the hook samples through a 0.025" tube and recording load vs. displacement. A 0.025" tube was used because that diameter simulates the load applied to the hook as it is being pushed through the delivery system at time of deployment. Thirty hook samples were used for the testing.

Summary: All 30 samples exceeded the acceptance criteria with the lowest tensile strength of 89.8 gm. Statistical analysis showed with 95% confidence that 99.9% of the samples will withstand 70 g of force prior to failure.

Corrosion/Fatigue Testing	While cardiac function has a very low impact on the IVC diameter, pulmonary function can produce a measurable IVC diameter change of approximately 1mm. Cyclic stresses and a corrosive environment could lead to filter fracture. In order to pass fatigue testing, the Recovery Filter must withstand cyclic stresses comparable to 10 years of pulmonary output in a simulated environment. Sixteen filters were subjected to 36 million cycles with 1mm deflection in an 18.9mm diameter tube submerged in mammalian isotonic Ringer' solution. In order to pass the test, there must be no evidence of cracks, wire deformation or any sort of physical damage to the filter under visual inspection. Summary: All filters were inspected following the testing. There were no cracks, wire deformation or any other physical damage to any of the samples. The results show that the Recovery Filter is able to withstand the stress caused by 10 years of pulmonary cycles and maintain integrity despite the corrosive environment.

Radial Strength Testing

Radial strength measurements were conducted to determine the force that the Recovery Filter applies to the venous wall. Since the ideal radial strength is not known, a comparison was made to the radial strength of the SNF filter. The SNF has been marketed for more than 10 years with no known clinical complications caused by excessive radial strength. In order to pass this test, the Recovery Filter must have a radial strength equal to or less than that of the SNF.

First, the filters were measured:

Filter	Leg Span (mm)	Arm Span (mm)
SNF	38	Not applicable
Recovery Filter	31	28

Since the dimensions of the Recovery Filter and the SNF are different, the same deflection was equivalent to a different IVC diameter according to the following formula:

(1) [Leg Span] – [2 x deflection] = IVC diameter
(2) [Arm Span] – [2 x deflection] = IVC diameter

To make a valid comparison between the two filters, the results for radial strength had to be calculated for the same IVC diameter. Vessel diameters of 17, 24 and 28mm were selected for comparison.

The results are displayed below:

Radial Strength (grams)

	28mm IVC	24mm IVC	17mm IVC
Recovery Arms	0.0	1.4	3.9
Recovery Legs	0.3	0.7	1.3
SNF long legs	2.7	3.5	4.2
SNF medium legs	3.1	4.1	4.8
SNF short legs	4.6	5.9	7.5

Summary: The results show that the Recovery Filter has a lower radial strength than the SNF, which meets the acceptance criteria of this test. While these results indicate that the Recovery Filter is less likely to cause injury to the IVC wall, the migration test results provided in this submission show that the hooks of the modified filter have sufficient radial strength for proper hook engagement to the IVC wall.

Simulated Use Study	Simulated use in an *in vitro* model was used to evaluate ease of deployment, filter centering, pushabilty and accuracy of placement for the Recovery Filter. Filters were deployed through a 70 degree iliac bifurcation into a 21mm Silastic tube, simulating worst case femoral delivery in an IVC. The model was submerged into a 37 degree +/- 2 degrees C water bath to simulate the human environment. The table that follows notes the acceptance criteria and results for each test.

Simulated Use Study (continued)

The key is:

1 = Excellent	Negligible forces
2 = Good	No significant forces
3 = Fair	Minor to moderate forces
4 = Poor	High forces

Test Performed	Acceptance Criteria	Comments
Dilator Removal	The ease of withdrawing the dilator from the sheath, through the marker bands and the hub must rank at 1 or 2 for all samples.	All 30 samples were ranked at 1. The modified device meets the acceptance criteria.
Sheath/Y-body Connection	The force required to connect the Y-body to the sheath hub must rank at 1 or 2 for all samples.	All 30 samples were ranked at 1. The modified device meets the acceptance criteria.
Filter Advancement into Sheath	Pushing the filter from the storage tube past the hub must rank at 1 or 2 for all samples.	Twenty-five of the 30 samples were ranked at 1 and the remaining 5 ranked at 2. The modified device meets the acceptance criteria.
Filter Advancement through Sheath and Past Marker Bands	Advancing the filter through the tortuous bend of the iliac model and past the marker bands must rank at 1 or 2 for all samples.	Twenty-six of the 30 samples ranked at 1 and the remaining 4 samples ranked at 2. The modified device meets the acceptance criteria.
Deployment	The force required to deliver the filter out of the end of the sheath and into the IVC must rank at 1 or 2 for all samples.	Twenty-two of the 30 samples ranked at 1 and the remaining 8 samples ranked at 2. The modified device meets the acceptance criteria.
Centering Results	All filter tips must be at a minimum of 1/3 the diameter of the IVC from the vessel model wall, i.e., in a vessel diameter of 12mm, the filter tip must be at least 4mm from the vessel wall.	All 30 samples centered properly in the vessel model. The modified device meets the acceptance criteria.

Spline Glue Joint Tensile Test

As noted previously, the spline is glued to the pusher pad using Loctite, a common adhesive. To ensure that the spline is adequately bonded to the pusher pad, tensile testing was performed. In order to pass the test, all 15 samples must withstand 3 lb. tensile force.

Summary: All 15 samples met the acceptance criteria. The minimum tensile force was 26.8 lb. with an average tensile strength of 32.1 lb.

Clinical Experience

Murray Asch, M.D., FRCPC, has been using the Recovery Filter in his clinical practice at Mount Sinai Medical Center in Toronto, Ontario since April 25, 2000 under a protocol consistent with the Special Access regulations found in Part 2 of the Food and Drugs Act of Canada.

His protocol, provided in Attachment 5, was originally approved on October 22, 1999 by the Mount Sinai Hospital Research Ethics Board and continues to receive approval each year (the most recent approval letter is provided in Attachment 5). An informed consent, also approved by the Mount Sinai Hospital Research Ethics Board and provided in Attachment 5, is used. Additionally, the rights of the patients are protected under the 1983 version of the Declaration of Helsinki. Dr. Asch complies with the Special Access regulations and Section 59 (mandatory problem reporting) of the Food and Drugs Act of Canada.

The objective of Dr. Asch's protocol is to provide his patients with a vena cava filter for temporary use in those cases where a permanent filter is not required. **There is no request to change the indication for use for the modified device subject to this 510(k).** However, Dr. Asch's data relative to complications during filter placement, recurrent pulmonary embolism, death, filter migration, etc. provide clinical data to support a determination of substantial equivalence as a permanent filter.

In total, Dr. Ash has received approval to implant the filter in 80 patients. As of the time of this submission, Dr. Asch has implanted the Recovery Filter in 35 patients. The data for those patients are presented in this submission.

Clinical Experience (continued)

Demographics

Thirty-seven patients were consented to receive the Recovery Filter. One patient was excluded because the vena cava was too large and one patient was excluded due to a congenital interruption of the vena cava therefore, 35 patients received the filter.

Patients ranged in age from 19-83 years with an average age of 53 years. There were 18 males and 17 females. Males ranged in age from 28-83 years (average age was 52 years). Females ranged in age from 19-81years (average age was 54 years).

Physical Examination and Medical History

All 35 patients who received a filter met one or more of the following criteria:

1. Patient has documented DVT and/or PE and is contraindicated for antiocagulant therapy at the time of filter placement;
2. Patient is at high risk of developing DVT and/or PE and is contraindicated for antiocagulant therapy at the time of filter placement;
3. Patient has documented DVT and/or PE and can be anticoagulated but is at high risk of severe morbidity from another PE.

DVT and/or PE was documented by CT, ultrasound or venogram. The three patients with false positive results received a filter since they were in the high risk category.

	%	N
Confirmed DVT	54.3	19
Confirmed PE	17.1	6
Confirmed DVT and PE	20.0	7
False positive for either PE or DVT	8.6	3
TOTAL	100.0	35

Physical examination and medical history showed that many of the patients had more than one risk factor for thromboembolism, including immobilization, malignancy, postoperative status, previous history of DVT, limb trauma and cardiac disease.

Clinical Experience (continued)

Filter Placement

The filter was placed according to the Instructions for Use provided in this submission. Filter location (apex of filter) in reference to the lumbar spine was confirmed by CT or venogram and recorded in the patient records.

Implant Procedure Difficulties

Twenty-two implant procedure difficulties were experienced in 35 implant procedures as noted below:

	%	N
Difficulty releasing device	28.6	10
Tilting of filter 20 degrees or more	14.3	5
Device did not fully open	11.4	4
Asymmetrical distribution of filter elements due to user error	2.9	1
First filter did not deploy: 2nd did not fully open	2.9	1
Difficulty releasing device and did not fully open	2.9	1
Misplacement of filter	0.0	0
Difficulty advancing device	0.0	0
Filter fracture	0.0	0
Penetration of IVC wall by filter elements	0.0	0
Hematoma around IVC	0.0	0
Thrombosis at access site	0.0	0
No difficulties experienced	37.1	13
TOTAL	100.0	35

An investigation determined that the filter spline was being over-polished during manufacture, which was thought to be the cause of release difficulties and partial device opening. The polishing process was modified after Patient #23 received the filter. No incidences of difficult release or partial device opening have been reported since the polishing change. There were no incidences of hematoma formation, A-V fistula or DVT at the insertion puncture site.

Patient Deaths

Three of the 35 patients have expired. None of the deaths were related to the implant procedure or the filter.

Clinical Experience (continued)

Post-implant Evaluation

Dr. Asch evaluates each patient just prior to device removal. Twenty-seven patients were evaluable.

	%	N
Filter removed	77.1	27
Filter not yet removed	14.3	5
Deaths	8.6	3
TOTAL	100.0	35

A pre-removal cavagram or CT indicated thrombus was present in the filter for 7 of the 27 evaluable patients. Nineteen patients showed no evidence of thrombus. One filter was not evaluated because the filter was removed during resection of the vena cava, caused by complications of tumor resection.

Stability of the filter was determined prior to removal. Nine patients experienced some change in filter placement (when compared to the cavagram performed immediately following filter deployment) or experienced some disruption of the caval wall. The cavagram for one patient showed that one filter arm was broken and that one hook was missing (discussed further below). None of the patients were symptomatic.

	%	N
1-2 filter legs incorporated into caval wall	11.1	3
Transmural incorporation	3.7	1
Filter leg outside vessel lumen	3.7	1
Questionable caval narrowing at filter site	3.7	1
Mild caval stenosis	3.7	1
Increased tilt from baseline with slight penetration of wall	3.7	1
Migration of 4cm	3.7	1
Filter arm fracture with missing leg hook	3.7	1
No change in filter placement or disruption of caval wall	63.0	17
TOTAL	100.0	27

Clinical Experience (continued)

Patient #9

One filter migration (4cm) was reported (Patient #9) 17 days post-procedure. The attending physician had determined that the patient was indicated for anticoagulation therapy so the filter was to be removed. The patient was taken to the angiography suite for evaluation just prior to filter removal. When the pre-removal cavogram was performed, Dr. Asch noticed that the filter contained a large amount of clot and had migrated to the top of the renal ostium. The filter and clot were removed in the same manner Dr. Asch used to remove the Recovery Filters in other patients and the patient suffered no ill effects.

Patient #33

One patient who received a filter, was at the end of her third trimester of pregnancy at the time of filter placement (Patient #33). The filter was placed with no complications at level L1-L2 of the lumbar spine. The patient delivered a healthy baby without complications.

Seventy-six days after filter placement, Dr. Asch performed a cavagram just prior to filter removal. The cavagram showed that one of the filter arms was broken and in a position superior to the other filter arms. The cavagram showed that the filter remained at L1-L2 (it had not migrated).

The filter with the broken arm was removed in the normal manner. Upon removal, it was noted that one of the leg hooks was missing. Confirmation of its location could not be definitively made however, the hook is believed to be embedded in the bony tissue surrounding the vertebrae. The patient suffered no adverse events.

An evaluation of the filter showed that it met all of its design and dimensional requirements. A review of the medical procedure associated with the arm fracture showed that the filter was deployed infrarenal, into a depressed vena cava in a pregnant women near the end of her third trimester. The filter deployed properly with the arms/legs engaging in the caval wall.

In the infrarenal position, the filter may be subject to uterine compression and significant movement of surrounding tissue and organs during childbirth. It is the stresses associated with childbirth on a filter deployed in this location that presents the most probable cause of the severe deflection of the arm resulting in fracture. In addition, these stresses are thought to have caused

Clinical Experience (continued)

caval penetration of the filter leg, allowing the hook to embed in the bony tissue of the vertebrae.

A precaution has been added to the Instructions for Use which states that a suprarenal position for filter placement should be used in women who are pregnant or of childbearing age. This statement was added as suggested in the "American College of Radiology (ACR) Standard for the Performance of Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism", effective January 2001.

Summary

As noted previously, Dr. Asch implanted the filter only in those patients who did not require a permanent filter. The average implant time for all patients who received the filter was 58 days (minimum 5 days, maximum 134 days).

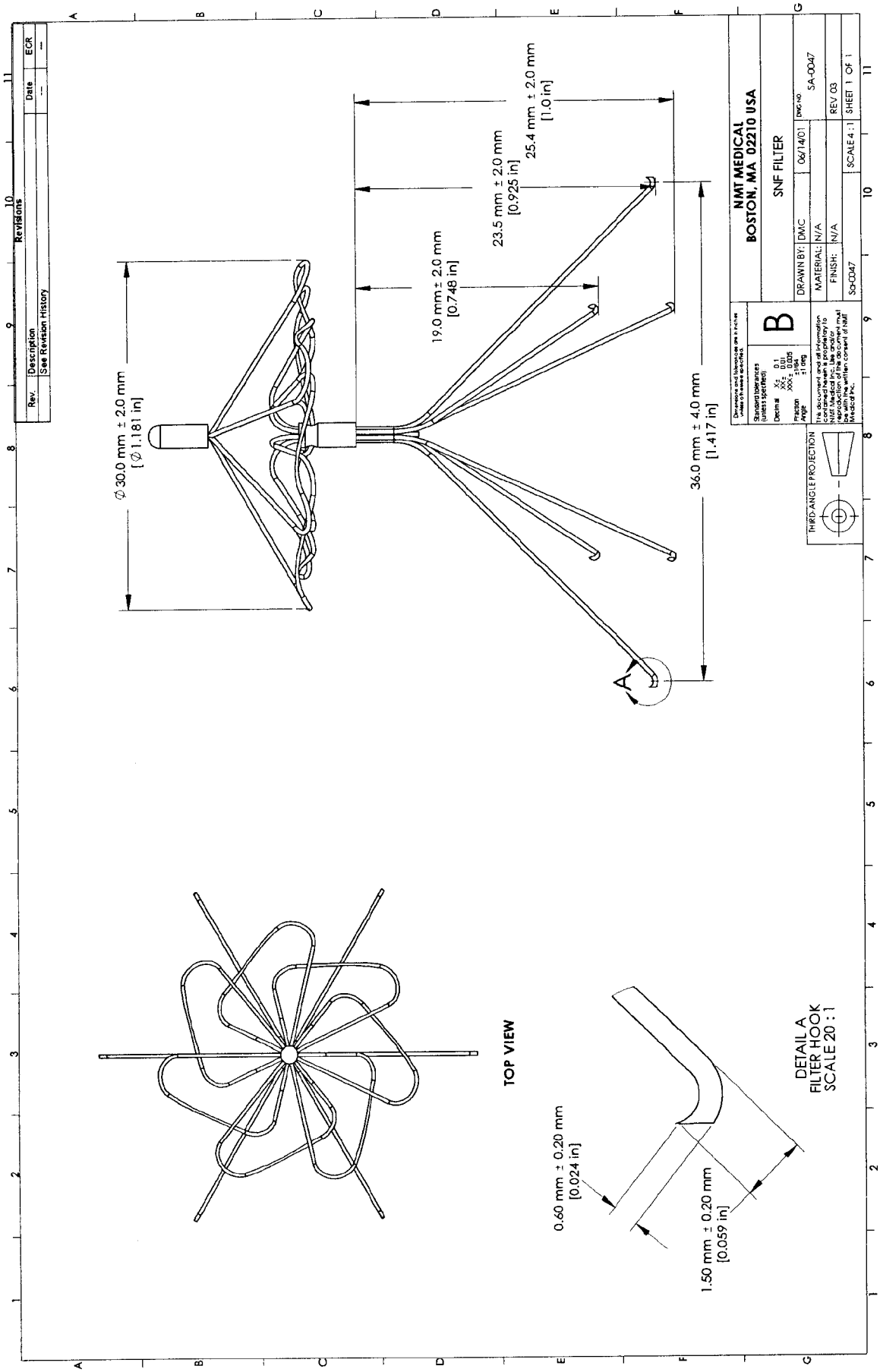
The Recovery Filter remained implanted for 26 days or more in 21 of the 35 patients who received the filter (26-134 days). During that time, there were no reported incidents of PE, death associated with the filter or filter occlusion. In the case of the one migration incident and one incident of filter arm and hook fracture, there was no association with any clinically significant events.

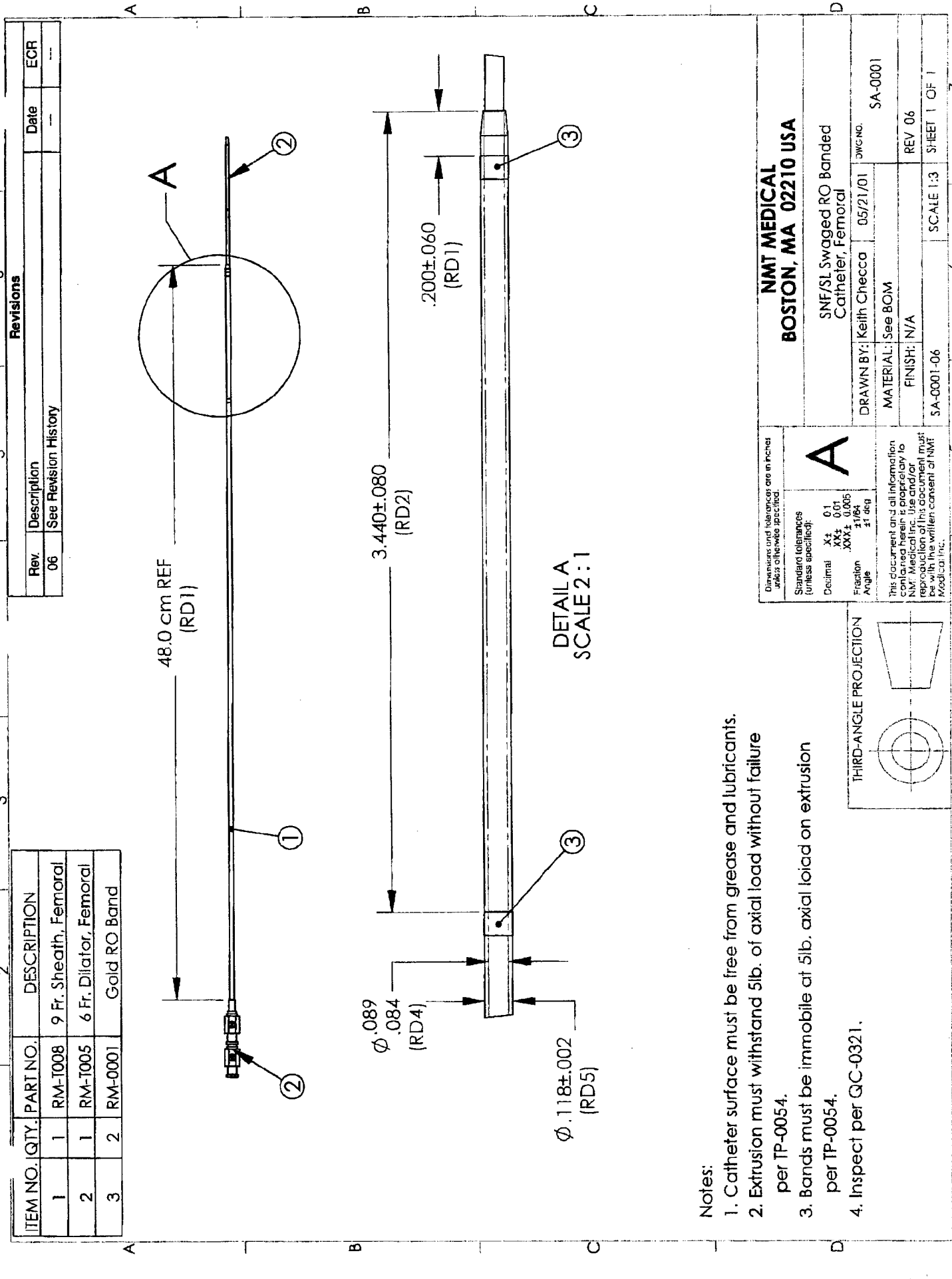
Packaging	The packaging for the modified device is the same as that of the Bard predicate device. The introducer catheter (with dilator) is packaged in a protective tube and placed in a Tyvek/film pouch (labeled at Kit A). The storage tube which contains the filter and the delivery catheter is packaged in a separate Tyvek/film pouch (labeled as Kit B). Both pouches are then placed in a large Tyvek/film pouch with the Instructions for Use and packaged in a fiberboard box.
Shelf Life	The glue joint added to the modified delivery system (spline to pusher pad) requires that stability testing be performed on the modified device. Accelerated aging (followed by real-time aging) will be performed to support a 3-year shelf life, the same expiry period as the Bard predicate.
Sterilization	The modified device is sterilized using ethylene oxide (as is the Bard predicate) with a Sterility Assurance Level (SAL) of 10^{-6}. Sterilization is performed at the C.R. Bard, Inc. facility in Covington, Georgia, Establishment Registration Number 1062335. Sterilization cycles are validated in accordance with ANSI/AAMI/ISO 11135-1994 "Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization". Ethylene oxide (EtO) residuals remaining on the device after one complete sterilization cycle are within the limits per ISO 10993-7 in conjunction with AAMI TIR 19-1998.
Declaration of Conformity	A Declaration of Conformity with design controls is provided in Attachment 6.
510(k) Summary	The Summary of Safety and Effectiveness is provided in Attachment 7.
Truthful and Accuracy Statement	A certification as to the truthfulness and accuracy of the data reported in this submission is provided in Attachment 8.

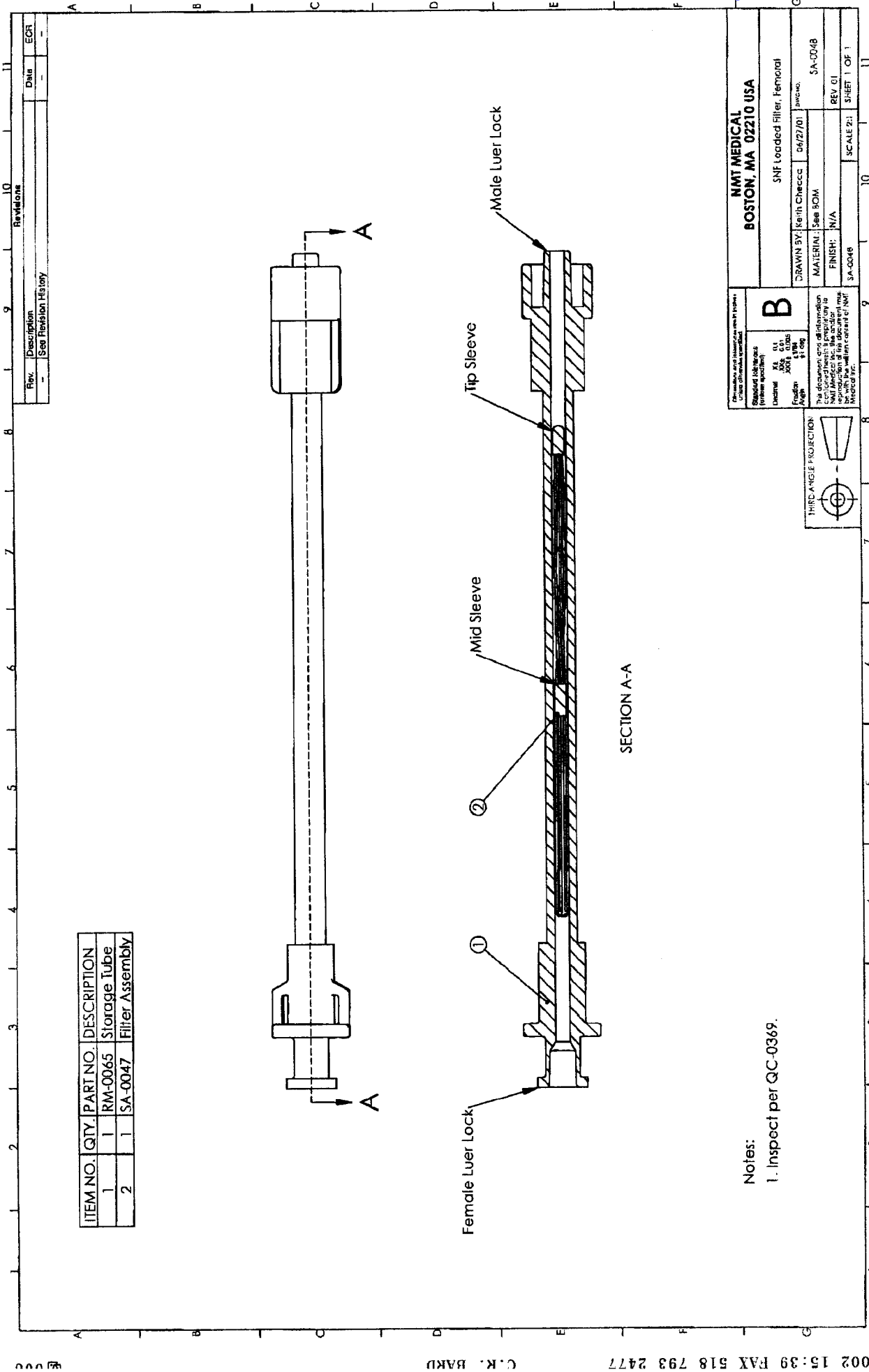
Attachment 1

Bard SNF/SL (Bard predicate)

Drawing of SNF Filter
Drawing of Delivery Catheter
Drawing of Loaded Storage Tube


Revisions
Rev. Description Date ECR
See Revision History
Ø 30.0 mm ± 2.0 mm
[Ø 1.181 in]
19.0 mm ± 2.0 mm
[0.748 in]
23.5 mm ± 2.0 mm
[0.925 in]
25.4 mm ± 2.0 mm
[1.0 in]
36.0 mm ± 4.0 mm
[1.417 in]
A
NMT MEDICAL
BOSTON, MA 02210 USA
SNF FILTER
DRAWN BY: DMC
06/14/01
DWG NO SA-0047
MATERIAL: N/A
FINISH: N/A
REV 03
Sd-0047
SCALE 4 : 1
SHEET 1 OF 1
THIRD-ANGLE PROJECTION
TOP VIEW
0.60 mm ± 0.20 mm
[0.024 in]
1.50 mm ± 0.20 mm
[0.059 in]
DETAIL A
FILTER HOOK
SCALE 20 : 1

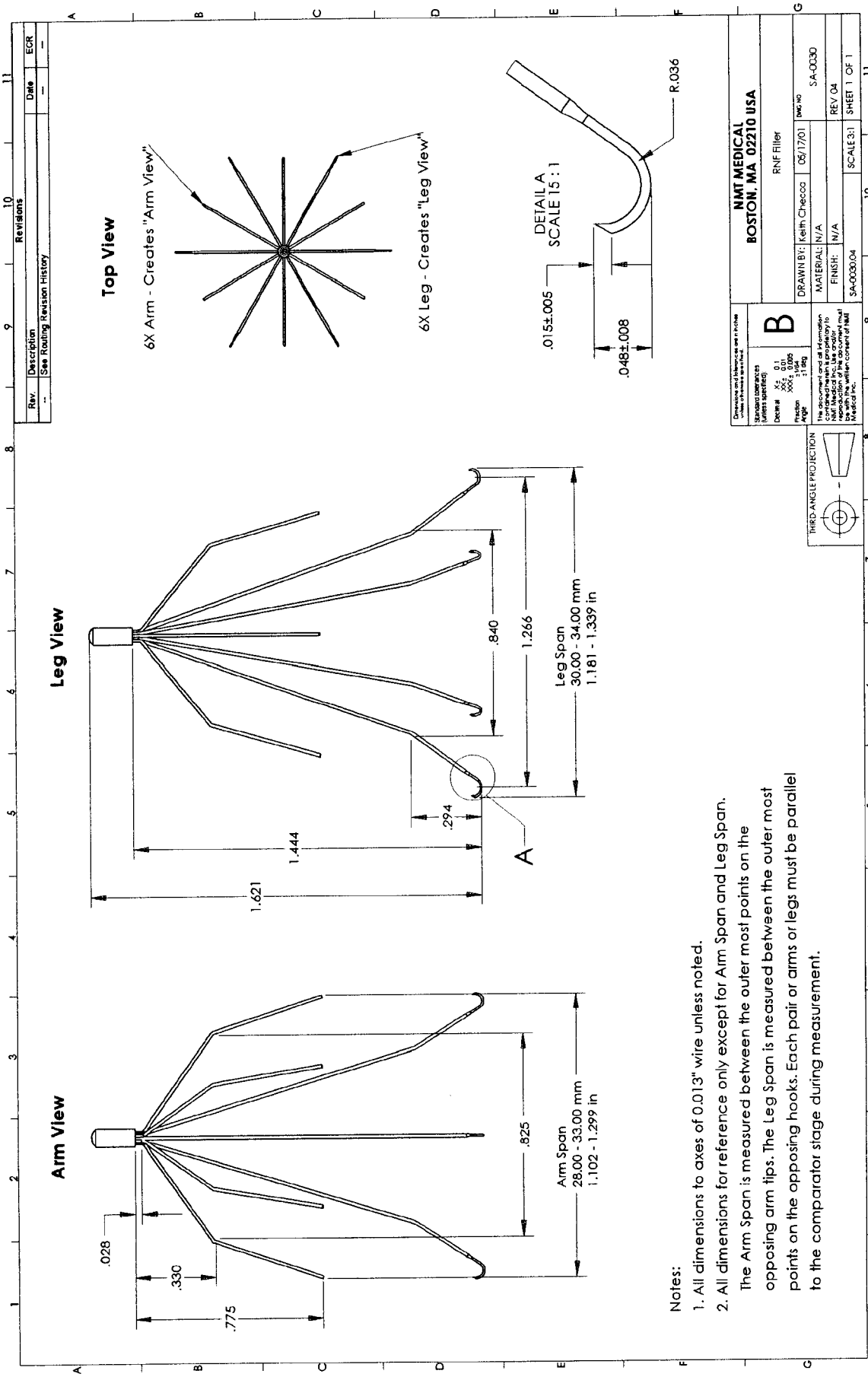


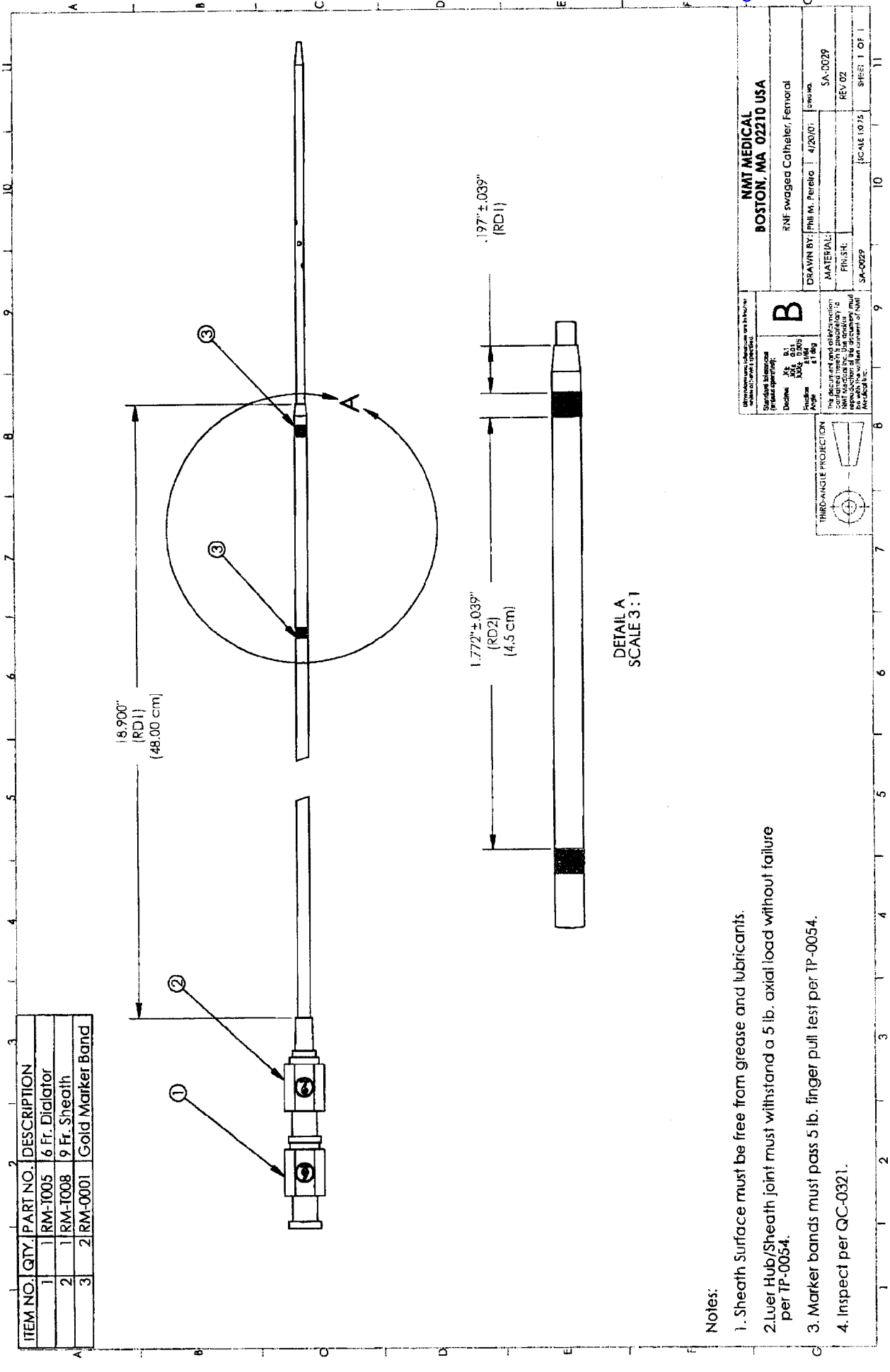


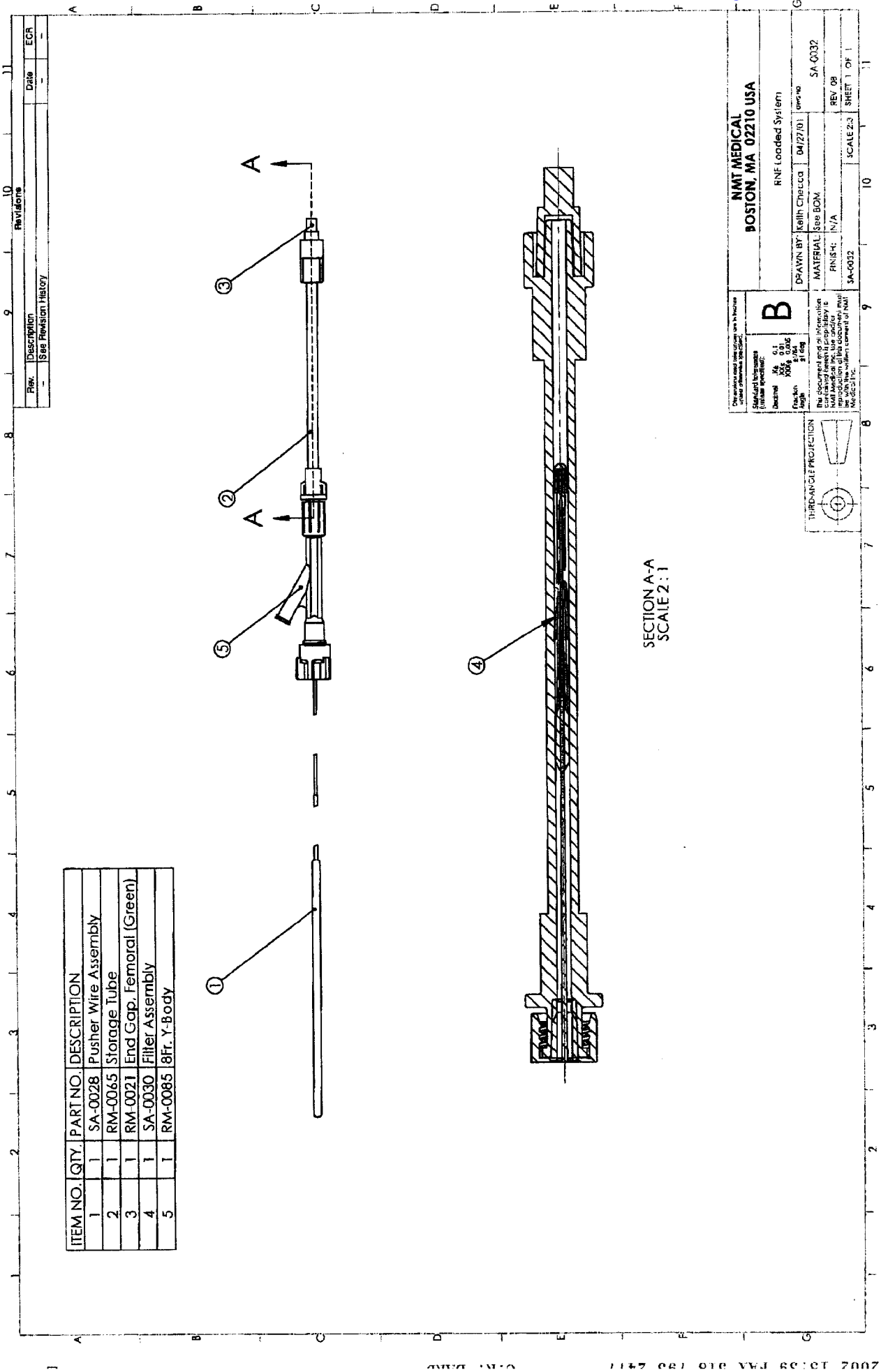
Attachment 1

Recovery Filter (Modified device)

Drawing of Recovery Filter
Drawing of Delivery Catheter
Drawing of Loaded Storage Tube


Revisions
Rev. Description Date ECR
-- See Routing Revision History -- --
Top View
6X Arm - Creates "Arm View"
6X Leg - Creates "Leg View"
DETAIL A
SCALE 15 : 1
.015±.005
.048±.008
R.036
Leg View
.840
1.266
Leg Span
30.00 - 34.00 mm
1.181 - 1.339 in
.294
1.444
1.621
A
Arm View
.028
.330
.775
.825
Arm Span
28.00 - 33.00 mm
1.102 - 1.299 in
Notes:
1. All dimensions to axes of 0.013" wire unless noted.
2. All dimensions for reference only except for Arm Span and Leg Span.
The Arm Span is measured between the outer most points on the opposing arm tips. The Leg Span is measured between the outer most points on the opposing hooks. Each pair or arms or legs must be parallel to the comparator stage during measurement.
THIRD-ANGLE PROJECTION
NMT MEDICAL
BOSTON, MA 02210 USA
RNF Filler
DRAWN BY: Keith Checco 05/17/01
MATERIAL: N/A
FINISH: N/A
SA-0030.04
SCALE 3:1
SHEET 1 OF 1
SA-0030
REV 04
B





Attachment 2

Titanium Greenfield Vena Cava Filter

Notice of 510(k) Clearance

CDRH

Premarket Notification

Return to Search

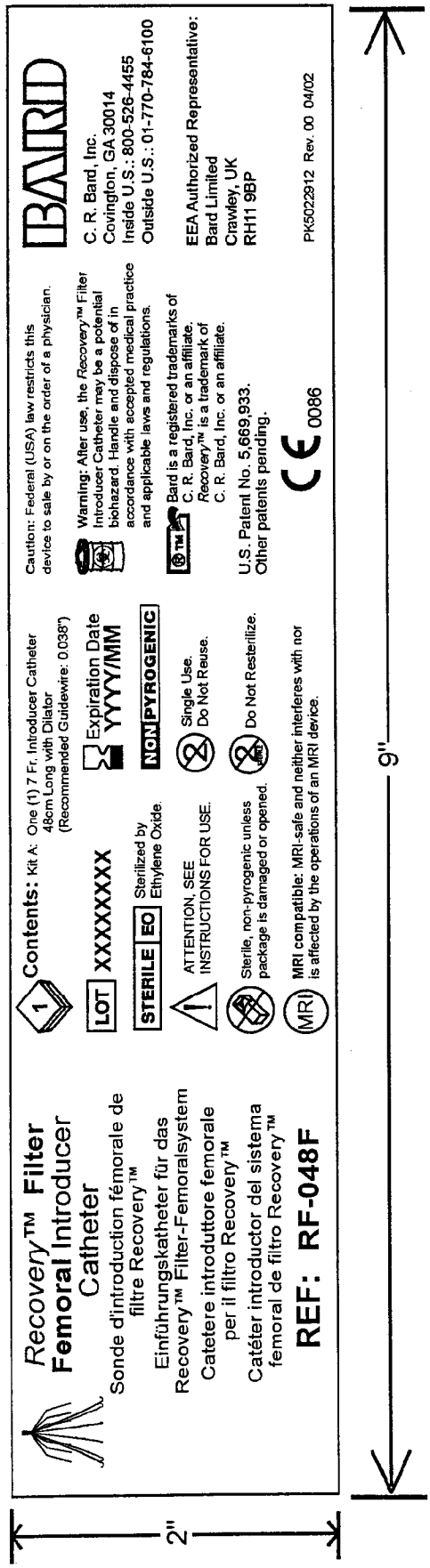
Device Classification Name	FILTER, INTRAVASCULAR, CARDIOVASCULAR
Regulation Number	870.3375
510(k) Number	K901659
Device Name	TITANIUM GREENFIELD(R) VENA CAVA FILTER W/HOOKS
Applicant	BOSTON SCIENTIFIC CORP. 480 PLEASANT STREET P.O. BOX 7407 WATERTOWN, MA 02272
Contact	SAVIN, MD
Product Code	DTK
Date Received	04/10/1990
Decision Date	11/08/1990
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Purged, no summary or statement
Type	Traditional
Reviewed by Third Party	No

Attachment 3

Kit A Pouch Label

PROPOSED LABELING

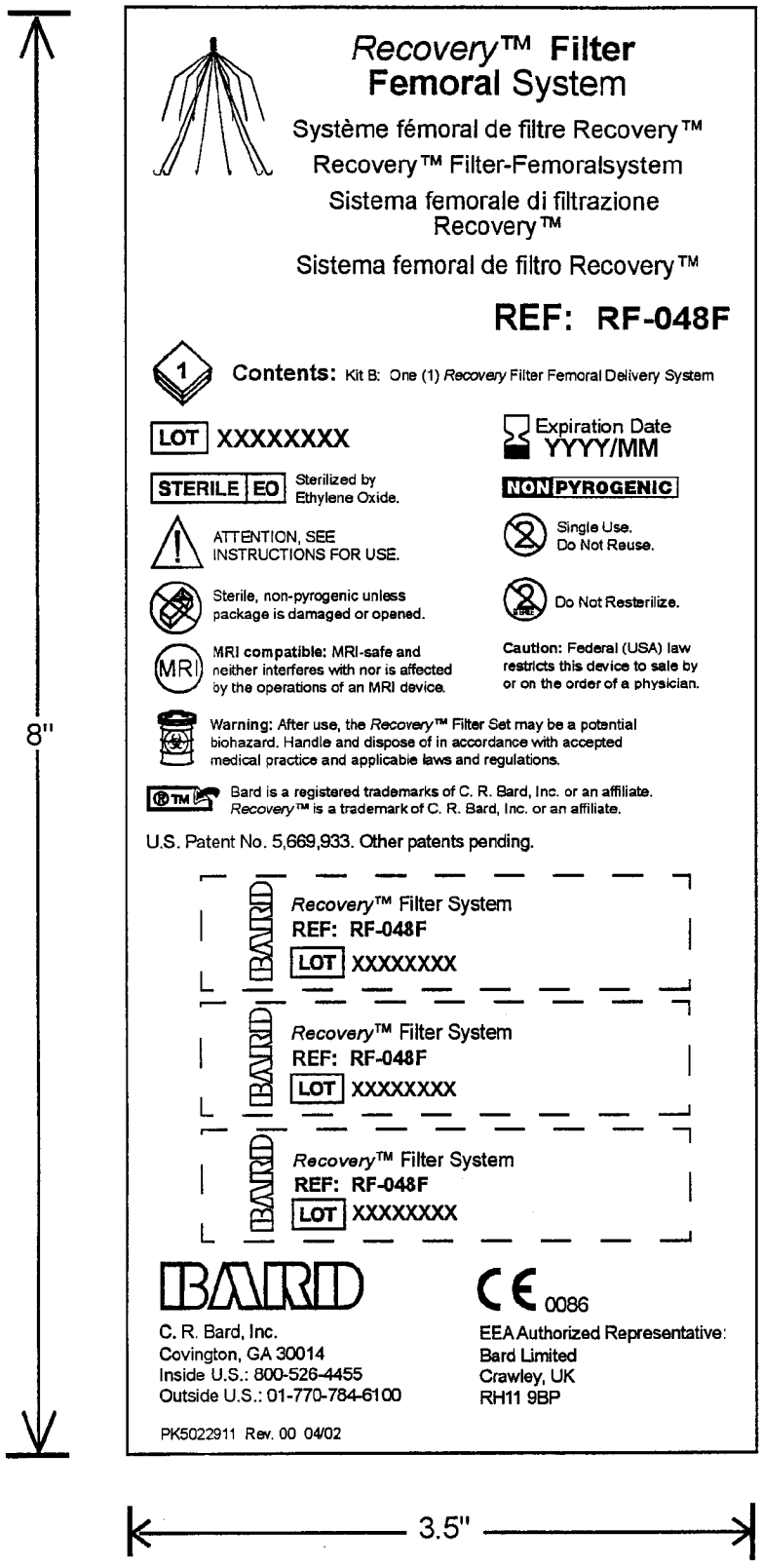
Recovery Filter Kit A Pouch Label



Attachment 3

Kit B Pouch Label

Recovery Filter Kit B Label

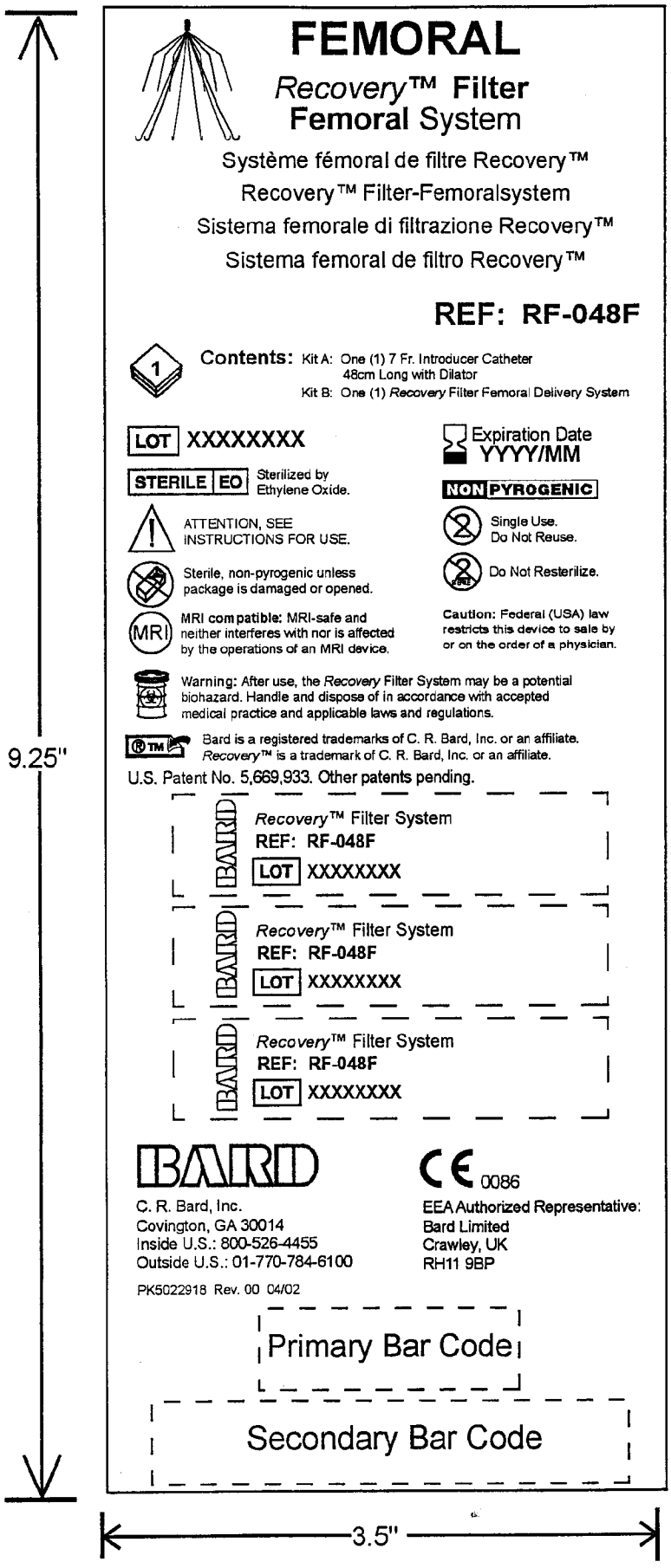


PROPOSED LABELING

Attachment 3

Outer pouch label—This pouch contains Kit A and Kit B

Recovery Filter Outer Pouch Label



PROPOSED LABELING

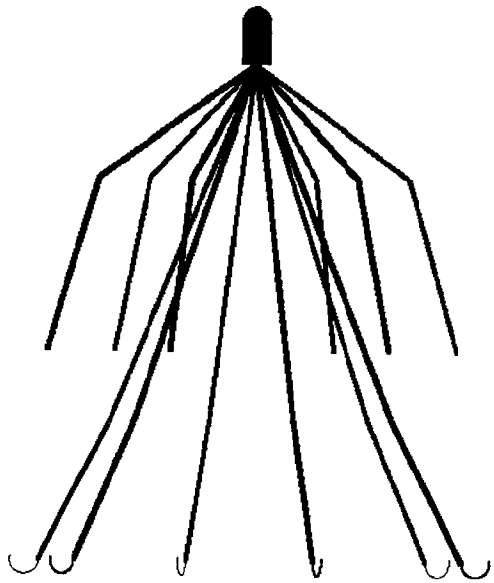
Attachment 3

Instructions for Use

Recovery™ Filter System for use in the Vena Cava

PROPOSED
LABELING

Instructions for Use



PK5100026 Rev. 000

A. General Information

Recovery™ Filter System

Expiration Date

Lot Number

Attention, See Instructions for Use.

Sterilized by Ethylene Oxide.

Nonpyrogenic

Single Use.
Do Not Reuse.

Do Not Resterilize.

Sterile, non-pyrogenic unless package is damaged or opened.

MRI compatible: MRI-safe and neither interferes with nor is affected by the operations of an MRI device.

Warning: After use, the *Recovery* Filter System may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Contents :
REF : RF-048F
Kit A : One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B : One (1) *Recovery* Filter Femoral Delivery System

Bard is a registered trademark of C. R. Bard, Inc. or an affiliate. *Recovery*™ is a trademark of C. R. Bard, Inc. or an affiliate.

U.S. Patent No. 5,669,933.
Other patents pending.

The *Recovery*™ Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the *Recovery* Filter provide excellent filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the *Recovery* Filter to be deployed with the filter tip centered and prevents the legs from crossing.

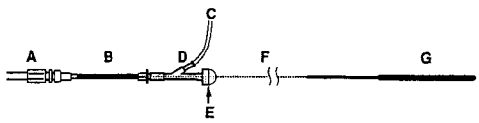
MRI Compatible: The *Recovery* Filter implant is MRI-safe and neither interferes with nor is affected by the operations of an MRI device.

B. Device Description

The *Recovery* Filter System consists of the Filter and Delivery System. The *Recovery* Filter consists of twelve, shape memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The *Recovery* Filter is intended to be used in venae cavae with diameters up to 28 mm.

The *Recovery* Filter Delivery System is illustrated in Figure A. The Delivery System consists of a 7 French I.D. introducer sheath and dilator, the *Recovery* filter, a storage tube with saline infusion port, and a pusher system. The *Recovery* Filter is packaged pre-loaded within the delivery storage tube.

Figure A. Recovery™ Filter System



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE
IMPORTANT: Read instructions carefully before using the *Recovery*™ Filter.

C. Indications for Use

The *Recovery*™ Filter is indicated for use in the prevention of pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Short-term risk for pulmonary embolism.

D. Contraindications for Use

CAUTION: If the corrected, inferior vena cava (IVC) diameter exceeds 28 mm the filter **must not be** inserted into the IVC.

The *Recovery* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with vena cava diameters greater than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.

If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer.

The *Recovery*™ Filter System is designed for femoral approaches only. Never use the *Recovery* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *Recovery* Filter orientation in the inferior vena cava.

Delivery of the *Recovery* Filter through the introducer sheath is advance-only. Retraction of the pusher wire during delivery could result in dislodgement of the Filter, crossing of filter legs or arms, and could prevent the Filter from further advancement within the sheath.

The *Recovery* Filter vena cava filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the vena cava (IVC), as the *Recovery* Filter vena cava filter cannot be safely reloaded into the storage tube.

F. Precautions

The filter should be placed in the superenal position in pregnant women and in women of childbearing age.

Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the inferior vena cava may follow the general course of such anatomic deformations.

G. Potential Complications

- *Migration of the filter.* This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized.
- *Perforation of the vena cava wall.* This may occur if improper insertion technique is not utilized.
- *Caval occlusion*. The probability of this occurring should be weighed against the inherent risk/benefit ratio for a patient who is experiencing pulmonary embolism, or who is likely to do so without intervention.

H. Equipment Required

The following equipment is required for use:

- One *Recovery* Filter and Delivery System that contains:
  - One 48 cm, 7 French I.D. introducer sheath and dilator set
  - One storage tube with pre-loaded *Recovery* Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

An entry kit consisting of a 0.038" 3 mm J-tipped guidewire, entry needle, #11 scalpel and 10 cc syringe is available from C. R. Bard, part number 4000E.

I. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

> **NOTE:** If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

> **NOTE:** The introducer catheter has radiopaque markers to assist in visualization and pre-deployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.

> **NOTE:** The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion the introducer catheter tip should be 1 cm below the lowest renal vein.

Filter Delivery

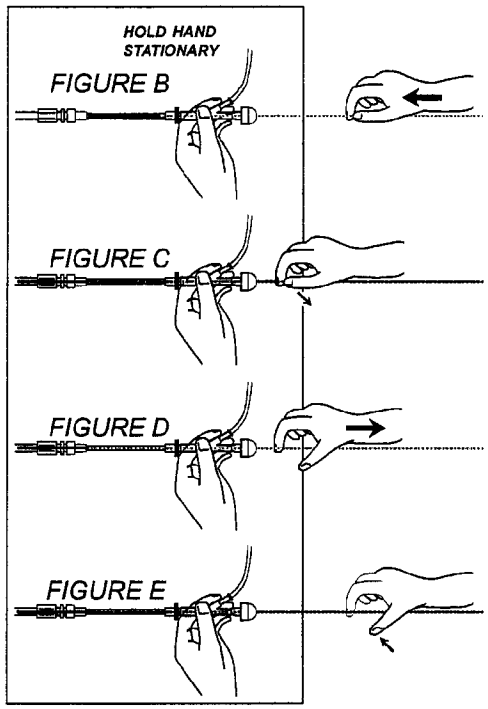
NOTE: Delivery of the *Recovery* Filter through the introducer sheath with the pusher wire is designed as advance-only. Retraction of the pusher wire during delivery can result in dislodgement of the Filter or crossing of the Filter legs or arms and could prevent the Filter from further advancement within the sheath. *Do not pull back on the pusher wire, only advance forward with filter in place.*

10. Remove the filter and delivery system from Kit B.
11. Connect a 500 mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to minimize reflux of saline, but not so tight as to prevent the pusher wire from advancing freely.

NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.

Advancement of Filter, Illustrated



13. Advance the Filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures B-E). *Do not pull back on the pusher wire, only advance the pusher wire forward.* For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.
14. Continue forward movement of the pusher wire until the Filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

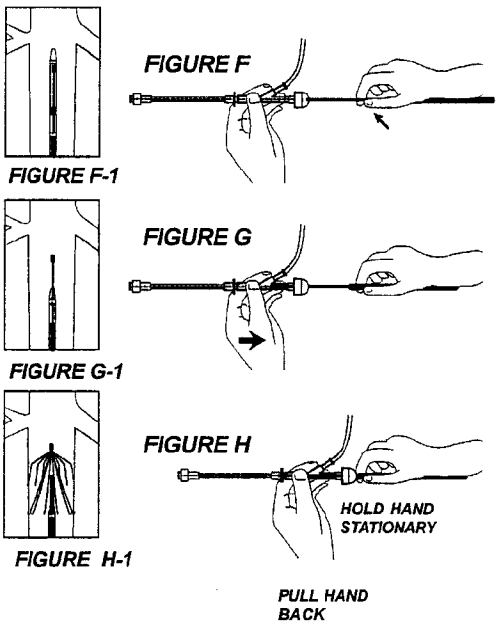
Filter Release/Deployment

15. Deliver and release filter as described below:

    Figure F: Firmly hold the pusher wire handle.
    Figure F-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

NOTE: Do not deliver the Filter by pushing it beyond the end of the introducer catheter. Instead, unsheathe the stationary Filter by withdrawing the introducer catheter as described below.

Filter Release, Illustrated



Now release the Filter by unsheathing it in the IVC as follows:

Position the Filter tip 1 cm below the lowest renal vein.

Figure G: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.
Figure G-1: Unsheathing of Filter in IVC.

Figure H: The position of the hands at the completion of the unsheathing process.
Figure H-1: The Filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and delivery catheter assembly and pulling back on the pusher wire.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

18. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
19. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

J. How Supplied

Each *Recovery*™ Filter is supplied preloaded in its storage tube. Each *Recovery* Filter is sterile and nonpyrogenic unless package is damaged or opened, and is ready to be **used for a single use only.** The storage tube and delivery system are preassembled. If the filter is inadvertently discharged, **do not attempt to re-sterilize or reload it.**

Warning: After use, the *Recovery* Filter accessories and insertion supplies may be a potential bichazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The *Recovery* Filter should be stored in a cool (room temperature), dry place.

L. Warranty

Bard warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in **Bard's** sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL **BARD** BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

REFERENCES

American College of Radiology (ACR), Standard for the Performance of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism. January 2001.

Labeling Issue Date: 04/02

In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available. (Inside U.S.: 800-526-4455; Outside U.S.: 01-770-784-6100)

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

BARD
C.R. Bard, Inc.
Covington, GA 30014
Inside U.S.: 800-526-4455
Outside U.S.: 01-770-784-6100

PK5100026 Rev. 000

Attachment 4

Indications for Use

Indications for Use Statement

Device Name	Recovery™ Filter System
Indications for Use	The Recovery™ Filter System is indicated for use in the prevention of pulmonary embolism via placement in the vena cava in the following situations: Pulmonary thromboembolism when anticoagulants are contraindicated. Failure of anticoagulant therapy in thromboembolic disease. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

Attachment 5

Special Access Approval Letter--
Canadian Clinical Experience

MOUNT SINAI HOSPITAL

Research Ethics Board

600 University Avenue, Room 1832
Toronto, Ontario, Canada, M5G 1X5
t: (416) 586-4875 f: (416) 586-4998
www.mtsinai.on.ca

November 8, 2001

Dr. Murray Asch
Department of Medical Imaging
Mount Sinai Hospital
Room 531
600 University Avenue
Toronto, Ontario

Dear Dr. Asch:

Re: MSH Reference # 01-0161-U
Removable Inferior Vena Cava Filter

The above-named study has received continued approval for the next 12 months from the Mount Sinai Hospital Research Ethics Board. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The REB must also be notified also of the completion or termination of this study and a final report provided.

If, during the course of the research, there are any serious adverse events, changes in the approved protocol or consent form or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Board. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Sincerely,

Irene V. Melissa, BSc, APMR
Manager, Research Ethics Board

For: Ronald Heslegrave, PhD
Chair, Mount Sinai Hospital Research Ethics Board

30 November, 2000
Original Date of REB Approval

30 November, 2002
Expiry Date of Protocol

Attachment 5

Special Access Use—
Clinical Protocol

Removable Inferior Vena Cava Filter

Goals

To assess a new design of removable IVC (inferior vena cava) filter to treat patients.

Background

IVC filters have been in widespread clinical use to prevent pulmonary embolism since the early 1970's. There have been a variety of designs, however the perfect filter has yet to be found. Long-term complications such as filter strut fracture or perforation cause hesitancy to use these devices in children and young adults, as there are no true long-term studies available. More recently, there have been attempts to design a filter that can be removed or retrieved after the period of risk of pulmonary embolism is over. In this way the potential risk for long-term complications can be avoided. Currently, temporary or retrievable devices must be removed prior to two weeks post insertion. With this very narrow window, there are relatively few patients who would truly be candidates for temporary filters.

This new filter design represents a significant benefit to patients in that it may be removed any time up to four (4) weeks following insertion (12 week removal data will be available shortly). Most patients with temporary contraindications to anticoagulation could be safely anticoagulated by 12 weeks following their surgery, trauma, or GI (gastrointestinal) bleed, for example.

Filter design

This new filter represents a modification of the Simon Nitinol Filter that has been in widespread clinical use for 10 years. This new, removable filter has been in development for four years, and during that time has undergone extensive bench top and animal testing. The filter has been found to be easy to deploy and remove. It has been found to be safe. Its clot capturing ability is equivalent to that of commercially available filters.

Placement

Filters will be placed in patients with the appropriate indication (see below), and then will be removed (if clinically safe and appropriate) within 12 weeks of insertion. This device can also function as a permanent filter as well; thus it may be left in situ when indicated.

Indications

The standard published indications for IVC filters are well accepted, and include contraindication to anticoagulation, complication of anticoagulation, and failure of anticoagulation. While these indications apply to this new filter design, the ability to remove the filter up to 12 weeks post implantation make this filter an excellent therapeutic option for patients with a temporary risk of pulmonary embolism and/or contraindication to anticoagulation. These patients include (but are not limited to): orthopedic patients, patients undergoing reconstructive surgery, trauma patients and post-op neurosurgical patients.

Approval

I have been in communication with Dr. William Freeland at the Health Protection Branch, Ottawa. He has already granted me special access approval for the device.

I have already informed a number of other individuals / agencies of my intentions. These include:

1) Lee Anne Harper-Femson, Director of Risk Management and Quality Assurance, Mount Sinai Hospital,
2) Janine Girard-Pearlman, Vice President, Mount Sinai Hospital,
3) Patrice Bret, M.D., Chief of Radiology, Department of Radiology, Mount Sinai Hospital.

Informed Consent

Standard informed consent will be obtained. A specific informed consent form has been created. As mentioned previously, this procedure is a well-accepted normal part of clinical practice. The only factor is lack of experience with this precise device in humans. During my discussion with patients, I will clearly state that this filter has never (or seldom, following the first patient) been used in humans before. I will clearly offer the patient an alternative (a currently approved permanent filter), with the understanding that there is no scientific knowledge of the results of having a filter in place for a long period of time.

Preceptorship

In order to minimize any adverse event related to this new device the team of scientists and physicians who have been involved in the development of this device from the outset will be in attendance during the initial deployments and removals.

Technique

The procedures will be performed using sterile technique and ultrasound guidance if necessary. The devices will be deployed and removed using standard techniques. As per routine practice, a venogram will be performed post removal to ensure that there are no caval tears.

Follow-up

As per standard clinical practice, routine follow-up abdominal radiographs to assess for filter migration obtained at 1 and 7 days then at 30 and 60 days will be performed. Additional follow-up will be performed on the physician's direction.

In any patient who demonstrates evidence of lower extremity edema suggestive of venous thrombosis / filter occlusion, appropriate imaging studies (Doppler US and enhance spiral CT) will be performed. A ventilation-perfusion scan or spiral CT pulmonary angiogram will be obtained in any patient suspected of developing new pulmonary emboli while the filter is in place (filter failure).

Any device-related adverse events or adverse events that are serious in nature will be reported immediately to NMT Medical Inc. and to Bard Canada Inc. In addition, these events will be reported to HBP, Ottawa immediately.

Attachment 5

Special Access Use—
Informed Consent

MOUNT SINAI HOSPITAL
600 UNIVERSITY AVENUE, TORONTO, ONTARIO, M5G 1X5

CONSENT FOR REMOVABLE INFERIOR VENA CAVA (IVC) FILTER

Introduction

You presently have blood clots in the veins of your legs or pelvis or have a high risk for blood clot formation in those veins. These may migrate to the lungs (or may have already done so) to create what is called a **pulmonary embolism** (blockage of a vessel supplying blood to the lungs). This disease is usually treated with blood thinners; however, in your case, blood thinners can prove ineffective or harmful (risk of bleeding). The standard alternative is to place a permanent filter in your vena cava (large vein in your abdomen, returning blood from your legs to your heart). It is a small metal umbrella shaped device used to trap blood clots before they reach the lungs.

Several types of filters have been implanted in the inferior vena cava for the past 30 years, and generally have been found to be quite safe and effective. Despite the many products available on the market, there is still no ideal filter. To be effective, a filter must trap all clots of significant size, and must remain in its initial position. Moreover, it must not become completely clogged which could lead to swelling of both legs (caval thrombosis). Ease of insertion is also important. A more ideal filter can be removed or retrieved after the period of risk of pulmonary embolism is over. In this way the potential risk for long-term complications of permanent filters can be avoided.

The Recovery Filter is a newly designed removable filter that has undergone extensive laboratory testing has been successfully tested in animals. This device has not been used yet in humans. The materials are exactly the same as those of the Simon Nitinol Filter which has been commercially available in the United States for 10 years (commercially available in Canada for 4 years). The design of the Recovery Filter is very similar to the Simon Nitinol Filter. The major difference between these two filters is that the Recovery Filter can be removed after the risk of pulmonary embolism has become acceptably low up to 12 weeks after implantation. It may also be left in place permanently. The Simon Nitinol Filter is a permanent filter and cannot be removed. The Recovery Filter and the Simon Nitinol Filter are manufactured by NMT Medical, Inc. and distributed by Bard Canada. The Recovery Filter is not currently available commercially to patients in Canada.

Presently, the Health Protection Branch of the Canadian government has given special access of the Recovery Filter to Dr. Asch for use in patients who could potentially benefit from a vena cava filter that can be removed.

Procedure

The procedure is essentially identical to the insertion and removal of the currently commercially available filters. The device is inserted in the Department of Medical Imaging (X-ray) under local anesthesia. A needle will be inserted into a vein in your leg to place a small tube (catheter). An angiogram of the inferior vena cava will be obtained in order to place the filter. The filter is then inserted through a small catheter in your leg. The entire procedure usually takes less than one half hour, and is minimally uncomfortable. You will then be sent back up to your room, where you will have to remain in bed for 4 to 6 hours (to allow the insertion site to heal). If your doctors feel that you may safely be started on blood thinners, or if your risk of blood clots is over, the filter will be removed in 4 to 12 weeks. This procedure is similar to the insertion. A special type of catheter will be inserted into the large vein in the right side of your neck, and the filter will be collapsed down into the catheter and pulled out through it. This procedure should take less than 30 minutes, with a similar short recovery. It may not be possible to remove the filter (it maybe full of blood clots). In this case, the filter will be left in place to act as a permanent filter.

Follow-up

In order to assess for filter migration (movement), you will undergo an X-ray of your abdomen at 1, 7, 30 and 60 days after the filter has been placed. This is standard clinical practice. If you develop any signs or symptoms suggestive of a complication or a problem, routine tests will be performed (CAT scan, ultrasound, nuclear medicine lung scan, angiogram, etc).

Potential Benefits

This device will prevent the development of pulmonary embolism during high-risk period when standard first line treatment (blood thinners) cannot be given. The main advantage of this device over any other currently available device is the elimination of potential long-term risks associated with the use of a permanent filter (strut fracture, filter occlusion, etc.) if the filter is removed after the temporary risk of pulmonary embolism has subsided.

Risks Related to the Filter
(These are the same risks associated with ALL current IVC filters)

1. Risks related to filter placement.

Potential complications related to filter implantation are:

a) The most common complication is that of a small bruise (hematoma) at the area in the upper leg where the filter was put in. This usually goes away without treatment in several weeks. This happens in less than 10% of patients. More severe damage to the vein or artery may occur, potentially requiring surgery to fix. This is very uncommon.
b) A blood clot may develop in the vein that was used to place the filter. This is quite rare, and if it occurs, may not cause any symptoms.
c) The filter may end up in an incorrect position. Alternatively, the filter may move after it has been placed. The position of the filter is usually not critical, and small amounts of movement (which usually only occur during the first few weeks) seldom causes a problem. You will have follow-up X-rays to check on the position of your filter.
d) You may have (or develop) an allergy to the X-ray dye that is used during the procedure. The most common symptoms of this are hives (an itchy skin rash) that is temporary. More serious reactions are very uncommon.
e) Damage (usually temporary) maybe caused to your kidneys as a result of the X-ray dye. This is very rare, and is usually as a result of abnormal kidney function before the procedure.
f) During the procedure, some air may enter the vein and go to the lung. While this can be very serious, it is very very rare.

Potential long-term complications (if the filter is left in place) are:

a) The filter may work so well, that it gets completely full of blood clots. This may then interfere with blood flow from the legs, causing swelling (which maybe severe) in both legs. This happens in up to 5% of cases. Untreated, symptoms from this usually reduce on their own within several months. If it is safe to give you blood thinners, that may speed up improvement in your symptoms.
b) The filter may fail to work, allowing blood clots to go to your lung, causing more symptoms. This happens in less than 5% of cases.
c) A part of the filter may go through the wall of vena cava. While this has been shown to be fairly common on X-rays, it almost never leads to any symptoms.
d) The filter may move following placement. Small amounts of movement are not a problem, but there have been rare reports of filters moving into the heart (requiring surgical removal).
e) It may not be possible to remove the filter, so that it must be left in to act as a

permanent filter.

1. Risks related to filter removal

These are the same as that for the filter insertion.

1) Unexpected risks

Since a new filter configuration is being used, there might be risks yet unknown and potential complications that have not been described.

Compensation

You will not be financially compensated if you agree to receive this device.

Contact Information

Safety Issues:	Dr. Murray Asch MD, Interventional Radiologist	tel 586-5186
Patient Rights:	Camala Day, Patient Relations	tel 586-5066

Confidentiality

Any information learned about you during this study will be confidential and neither your name or any other identifying information will be made available to anyone other than the investigators.

Rights and Obligations

You may freely refuse to participate in this study and you will still receive the treatment to which you are otherwise entitled. In that case, you will receive one of the currently approved permanent IVC filters. However, if you agree to receive the Recovery Filter and sign the consent form, you are neither waiving your legal rights nor releasing the investigator, the manufacturer, the distributor or the hospital from their civil and professional liabilities.

1. I have read the above form.

2. I acknowledge that I have received adequate information and that I was given enough time to ponder this information and to seek advice.

3. I recognize that the medical and technical terms used were explained to my satisfaction and that all of my questions have been answered fully.

4. I recognize that my participation is voluntary and that I am free to participate.

5. I recognize that I have received a copy of this informed consent form.

_____
Patient's name

_____ _____
Patient's signature Date

_____
Witness's name

_____ _____
Witness's signature Date

Attachment 6

Declaration of Conformity with Design Controls

DECLARATION OF CONFORMITY WITH
DESIGN CONTROLS

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modifications were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Lynne Buchanan-Kopp
Senior Quality Assurance Engineer

June 28, 2002
Date

Manufacturing Facility

The manufacturing facility, Glens Falls Operations, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Pete Palermo
Corporate Director of Quality Control

Date

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modifications were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Lynne Buchanan-Kopp
Senior Quality Assurance Engineer

Date

Manufacturing Facility

The manufacturing facility, Glens Falls Operations, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Pete Palermo
Corporate Director of Quality Control

6/28/02
Date

Attachment 7

Summary of Safety and Effectiveness

IMPRA
A Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740
TEL: 800-321-4254
480-894-9515
FAX: 480-966-7062

IMPRA

510(k) SUMMARY OF SAFETY AND EFFECTIVENES INFORMATION

A. Submitter Information:

Submitter's Name: C.R. Bard, Inc., Impra
Submitter's Address: 1625 West 3rd Street
Contact Person: Kay Fuller
Contact Person's Telephone Number: (480) 303-2539
Contact Person's FAX Number: (480) 449-2546
Date of Preparation: July 8, 2002

B. Device Name:

Recovery™ Filter System

C. Predicate Devices:

Simon Nitinol Filter/Straightline™ System
Titanium Greenfield® Vena Cava Filter

D. Device Description:

The Recovery Filter System consists of a nitinol vena cava filter and a delivery system. The filter has two levels of filtration and is prepackaged in a storage tube. The delivery system consists of a 7 Fr ID introducer sheath and dilator and a pusher system. Both components of the system are packaged in Tyvek/film pouches.

BARD

E. Intended Use:

The Recovery Filter is indicated for use in the prevention of pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy in thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

F. Technological Characteristics Summary:

The filter consists of twelve, shape memory nitinol wires emanating from a central nitinol sleeve. The wires form two levels of filtration: six arms and six legs. The delivery system is used to place the filter into the inferior vena cava.

G. Performance Data:

Bench testing was performed per the FDA guidance document, "Guidance for Cardiovascular Intravascular Filter 510(k) Submission". Testing showed that the Recovery Filter is substantially equivalent to the Bard predicate device.

Attachment 8

Truthfulness and Accuracy Statement

Labeling and Intended Use (continued)

The Bard predicate device labeling noted that NMT Medical, Inc. was the manufacturer and that C. R. Bard, Inc. was the distributor. Bard has purchased the filter line from NMT Medical, Inc. and is now the manufacturer as well as the distributor. NMT Medical, Inc. has been removed from the labeling for the Bard predicate and modified device labeling.

The "Warnings" section of the Instructions for Use for the modified device has been organized to include statements that are noted in various sections of the Bard predicate IFUs. No new warnings have been added to the modified device IFU except to warn the user against attempting to place the filter from a superior approach (jugular, subclavian or antecubital vein).

A precaution has been added to the IFU for the modified device per the "American College of Radiology (ACR) Standard for the Performance of Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism", effective January 2001 to note that filter placement in pregnant women or women of childbearing age should be suprarenal.

The "Delivery Tips" section for the various placement routes is not included in the modified device IFUs. Tips for femoral delivery are noted in the "Filter Delivery" section of the modified device IFU. The modified IFU is provided in Attachment 3.

EXHIBIT H

EXHIBIT A

Exhibit	Description	Category
553	Asch Deposition, 05/02/2016 - Exhibit 203 - 9/14/2002 Memo from Thomas Kinst to Recovery Filter Design History File Re. Recovery Filter Compassionate Use, Subject: "Conference call with Bard Peripheral Technologies regarding clinical assessment of Recovery Filter removal #5"	2
709	Brauer, 08/02/2017, Exhibit 1046 - Bard Simon Nitinol Filter, Postmarket Surveillance Study Amendment, August 10, 2014	2
876	Chanduszko Deposition, 04/23/2015 - Exhibit 17 - Pages 30-44 of Notebook No. 7013, Project: Recovery Filter Arm Fatigue Testing	1
905	Ciavarella Deposition, 03/01/2011 - Exhibit 07 - 12/20-12/23/2005 E-mail exchange b/w Walcott and Ciavarella Re. "G2 Caudal Migrations"	3
927	Ciavarella Deposition, 11/12/2013 - Exhibit 35 - Health Hazard Evaluation Memo from Ciavarella to Uelmen Re. "Recovery Filter - Consultant's report", dated 12/17/2004	2
945	Cohen, 01/25/2017, Exhibit 736 - Monthly Report, IVC Filters/Covered Stents, Janet Hudnall, April, 2004	2
1062	Edwards Deposition, 01/20/2014 - Exhibit 14 - BPV PowerPoint presentation entitled "BPV/AngioMed New Product Development Review Meeting - April 26, 2004"	2
1216	Ganser Deposition, 10/11/2016 - Exhibit 526 - Regulatory Affairs Manual Re. "Product Remedial Actions", RA-STD-002 Rev. 08, dated 10/12/2000	4
1221	Ganser Deposition, 10/11/2016 - Exhibit 533 - 2/15/2006 Health Hazard Evaluation from David Ciavarella to Gin Schulz Re. "G2 Inferior Vena Cava Filter - Migration"	4
1222	Ganser Deposition, 10/11/2016 - Exhibit 534 - PowerPoint Presentation for a meeting to analyze EVEREST and MAUDE data and provide justifications for proposed changes to G2 filter	2, 3
1295	Graves Deposition, 02/27/2014 - Exhibit 10 - 3/23/2006 E-mail exchange b/w Mickey Graves and Charlie Simpson, FEA on G2, regarding Historical FEA analysis	2
1517	Kessler Report - Based on the Fishbone analysis insufficient caudal anchoring is likely the root cause of caudal tilts and caudal migrations, and indirectly of penetrations and fractures.”	1, 2

1578	Kessler Report ETR-06-28-29, revision 0, project #8049, Caudal Migration Test Method Development and G2 Filter Resistance Test Report, 11/27/06	1, 2
1680	McDonald Deposition, 07/29/2016 - Exhibit 21 - 7/13/2015 Warning Letter from the FDA regarding the 11/25/2014 Inspection of the C.R. Bard facility in NY and the 11/18/2014-1/5/2015 Inspection of the BPV facility in AZ	4
1945	Schulz Deposition, 01/30/2014 - Exhibit 16 - 10/1/2006 E-mail from Nataile Wong to Several Re. "Fracture Docs"	3
1946	Schulz Deposition, 01/30/2014 - Exhibit 17 - 2/2/2006 E-mail from Gin Schulz to Several Re. "Minutes"	3
1951	Schulz Deposition, 01/30/2014 - Exhibit 5 - 1/31/2005 Memo from Peter Palermo to Kerry Chunko Re. "Quality Plan 2005"	2
2048	Sullivan Deposition, 09/16/2016 - Exhibit 437 - Document entitled "Failure Investigations/R002 History Review"	2, 3
2052	Sullivan Deposition, 09/16/2016 - Exhibit 446 - Draft of PowerPoint Presentation entitled "G2 and G2X Fracture Analysis", dated 11/30/2008	3
2059	Tessmer Deposition, 06/12/2013 - Exhibit 02 - Project Status Report Form for the Recovery Filter, Project No. 7081, initiated 7/1/2002 with the goal to "Investigate Migration"; FM0700160, Rev. 1.	2
2090	Tillman, 08/04/2017, Exhibit 1064 - NMT Medical, Inc. Document	2
2217	Williamson Deposition, 09/07/2016 - Exhibit 105 - Cover page entitled "Attachment 1.14", followed by the 1/23/2015 Memo from Ludwig to Chad Modra Re. "IVC Filters Retrospective Review", detailing the 2-year review of 939 filter complaints from 1/2013 to 1/2015, with a chart detailing whether the MDR classification changed for any complaints	2, 3
2243	Wong Deposition, 10/18/2016 - Exhibit 537 - 4/23/2004 E-mail from John Lehmann to Carr and Uelmen Re. "Draft data set for statistician"	3
2245	Wong Deposition, 10/18/2016 - Exhibit 540 - Confidential PowerPoint Presentation entitled "Recovery (Gen 1) - Fracture and Migration Complaint Update," dated 6/20/2006	3
2246	Wong Deposition, 10/18/2016 - Exhibit 541 - 8/4/2006 E-mail from Natalie Wong to Gin Schulz Re. "Updated RNF Draft Report"	3

2247	Wong Deposition, 10/18/2016 - Exhibit 542 - 12/2/2009 E-mail exchange b/w Sandy Kerns and Natalie Wong Re. "Filter Fractures"	3
2248	Wong Deposition, 10/18/2016 - Exhibit 543 - PAT PowerPoint Presentation entitled "G2 Caudal Migration Update," dated 3/2/2006, which Wong circulated via e-mail on 3/2/2006 to several for the presentation that afternoon	3
2249	Wong Deposition, 10/18/2016 - Exhibit 544 - 5/18/2006 Natalie Wong meeting documents, email re "Caudal Investigation" with attachments of G2 Caudal Report 05.18.06 and Caudal Pre-PAT minutes	3
2250	Wong Deposition, 10/18/2016 - Exhibit 545 - BPV's Failure Investigation Report on the G2 Filter - Caudal Migration, FIR-06-01-01, unsigned and forwarded by Wong to Gin Schulz for her review, in anticipation of the Friday deadline	2, 3
2251	Wong Deposition, 10/18/2016 - Exhibit 547 - 4/10/2006 High Importance E-mail from Cindi Walcott to Allen, Schulz, and McDermott Re. "FW: FDA Request for Information"	4
2252	Wong Deposition, 10/18/2016 - Exhibit 548 - 9/25/2007 E-mail from John Lehmann to John Van Vleet and John Reviere Re. "EVEREST FSR rev H and supporting redlines	1
2253	Wong Deposition, 10/18/2016 - Exhibit 549 - 5/27/2004 E-mail from Natalie Wong to Doug Uelmen Re. "Recovery Stats"	3
4327	Monthly Global PV Report - January 2006, date of memo, 02/10/2006	2, 3
5022	RD-LNB-087 Laboratory Notebook	2
5037	ETR-05-02-02 (Effects of Changes to the Recovery Filter & The Femoral Delivery System on Filter Stresses Based on FEA Analysis)	2
5189	July 10, 2002 IMPRA Recovery Permanent Special 510(k) (K022236)	4
5195	Nov. 30, 2004 Letter FDA to BPV re Recovery IFU and DDL	4
5232	RD-RPT-116 (RNF Migration Study) (Test report for RD-SOP-035.02) RD-RPT-116	1, 3
5233	RD-SOP-054.00 (Recovery Filter EnduraTEC Fatigue Testing SOP NMT)	1
5290	TD-00456 (EVEREST Study Final Report)	1

5296	G2 Filter Product Performance Specification, v.2	1
5301	ETR-05-01-06 Animal Model Evaluation of Recovery Filter G1A Femoral System Report	1
5302	TPR 05-01-13 G1A Recovery Filter Femoral System Design Verification and Validation Protocol	1
5303	ETR-05-02-05 (G2® DV&V summary testing)	1
5304	ETR 05-02-11 G1A Recovery Filter Femoral System Chronic Animal Study Report	1
5315	Phase 2 Design Review G1A Recovery Filter Femoral Delivery System	2
5316	Phase 3 Design Review (Design Review 3 & 4) G1A Recovery Filter Femoral Delivery System	2
5323	Aug. 8, 2005 FDA Grants BPV Conditional Approval for G2 Everest Study (G050134)	4
5324	July 8, 2005 BPV's original IDE submission re G2 Everest Study (G050134)	4
5325	Oct. 3, 2005 Letter BPV to FDA re G2 Everest Study (G051034) and Conditional Approval	4
5329	June 21, 2006 Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement	4
5333	Feb. 2, 2007 Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report	4
5334	Sept. 21, 2007 Letter FDA to BPV Questions re G2 Everest Study (G051304)	4
5335	Aug. 23, 2007 Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report	4
5336	Oct. 25, 2007 Letter BPV to FDA re Responses to FDA re G2 Everest Study (G051304)	4
5340	Oct. 31, 2007 BPV's G2 Filter Retrievable Traditional 510(k) (K073090)	4
5344	July 28, 2005 Letter FDA to BPV re AI re Modified Recovery (K050558)	4
5349	Mar. 2, 2005 BPV's Modified Recovery Filter Special 510(k) (K050558)	4

5354	Sept. 19, 2005 BPV's G2 Filter - Jugular Subclavian Delivery Kit Special 510(k) (K052578)	4
5361	Sept. 25, 2006 BPV's G2 Filter - Femoral Delivery Kit Special 510(k) (K062887)	4
5483	sopq1417500 Rev 1 -- Statistical Complaint Trending Procedure PMA Related sopq1417500 Rev 1 -- Statistical Complaint Trending Procedure PMA Related	3
5526	TPR-04-02-02 (Protocol for RNF Migration Testing v. Competitive) Test Protocol Number TPR-04-02-02 (Rev. 0) -- Characterization of the Recovery Filter (RF) - Migration Resistance	1
5539	G2 Caudual Migration Failure Investigation Report Aug. 4, 2005 G2 Filter Caudal Migration Failure Investigation Report (FIR-06-01-01) G2 Caudual Migration Failure Investigation Report	3
5560	Standard Operating Procedures / Division Operating Procedures -- CQA-STD-R002 Rev 11	2
5602	FDA CONTACT REPORT January 7 2010 FINAL	4
5691	BPV FDA 483 Update Response March 26, 2015.pdf	4
5706	September 3 2015 Update Response to Warning Letter issued July 13 2015.pdf	4
5851	TD-04698 Re_Retrospective IVC Filter Review.pdf	2, 3
5872	FDA Warning Close Out Letter	4
5874	Bard filter rate information December 2016	3
5877	1996 Memo from Veronica Price	4
5879	April 11, 2006 Letter to FDA re Caudal Migration	4
5880	March 23, 2006 Letter to FDA re G2 Caudal Migration	4
5881	May 11, 2006 Letter to FDA re Caudal Migration	4
5942	January 7, 2010 FDA Powerpoint Presentation	4

5949	ETR-06-05-02 (Test report re G2® Clot Trapping Efficiency)	1
5994	TD-04316 Nov. 4, 2015 FDA and Bard Teleconference	4
5995	TD-04326 Oct. 26, 2015 FDA and Bard Teleconference	4
6046	August 28, 2006 EVEREST Medical Monitor Adjudication Meeting Minutes	3
6061	Aug. 22, 2005 Internal FDA memo reviewing BPV's Responses to FDA AI re G2 (K050558)	4
6064	July 26, 2005 Internal FDA memo re BPV Responses to FDA AI re Modified Recovery (K050558)	4